

EXHIBIT A

Log No.	PrivLogControl	DocDate	Author	Recipient	CC	BCC	Description of Communication	Privilege Asserted	ProdBegDates	ProdEndDates	Basis of Challenge
Log 1	114	3/18/2005	John Lehmann and Richard Holcomb	David Ciavarella	Donna Passero, Esquire; Brian Barry; Chris Ganser		File folder regarding clinical data strategies for Recovery@ Filter with March 2005 report by Independent Consultant #1 and Richard Holcomb regarding clinical data strategies for Recovery@ Filter	Attorney-client privilege Work product			Bard's December 2004 Health Hazard Evaluation advised that Bard should evaluate a the possibility of clinical trial to assess the risks and benefits of the Recovery Filter in light of substantially higher reported failure rates. Bard then used Dr. Lehmann and Richard Holcomb to perform that assessment. There is no question that this assessment would have been performed in a substantially similar manner regardless of litigation and there were sufficient motivating business reasons for performing it. Bard should not be allowed to manufacture a privilege over a planned and required business activity by simply using in house counsel to outsource the work to "consultants." Thus Bard has failed to establish that the primary purpose of the communication was to obtain or provide legal advice, or that the communication was performed "because of" anticipated litigation. The <i>Phillips</i> court in found Joint Selection No. 26 discussing Dr. Lehman's and Mr Holcombs work regardign the clinical study strategies to not be protected. , <i>Phillips v. C.R. Bard, Inc.</i> , 290, F.R.D. 615, 652-53 (D. Nev. 2013)
Log 1	115	3/18/2005	John Lehmann	David Ciavarella	Richard Holcomb; Chris Ganser; Brian Barry; Donna Passero, Esquire.		Email from John Lehmann regarding Recovery@ Filter clinical data and attaching spreadsheet pursuant to 11/24/04 contract with the Bard legal department	Attorney-client privilege Work product			Bard's December 2004 Health Hazard Evaluation advised that Bard should evaluate a the possibility of clinical trial to assess the risks and benefits of the Recovery Filter in light of substantially higher reported failure rates. Bard then used Dr. Lehmann and Richard Holcomb to perform that assessment. There is no question that this assessment would have been performed in a substantially similar manner regardless of litigation and there were sufficient motivating business reasons for performing it. Bard should not be allowed to manufacture a privilege over a planned and required business activity by simply using in house counsel to outsource the work to "consultants." Thus Bard has failed to establish that the primary purpose of the communication was to obtain or provide legal advice, or that the communication was performed "because of" anticipated litigation. The <i>Phillips</i> court in found Joint Selection No. 26 discussing Dr. Lehman's and Mr Holcombs work regardign the clinical study strategies to not be protected. , <i>Phillips v. C.R. Bard, Inc.</i> , 290, F.R.D. 615, 652-53 (D. Nev. 2013)
Log 1	116	3/18/2005	Chris Ganser	Paula Pizzi			Forward of email from John Lehmann regarding Recovery@ Filter clinical data and attached spreadsheet pursuant to 11/24/04 contract with the Bard legal department	Attorney-client privilege Work product			Bard's December 2004 Health Hazard Evaluation advised that Bard should evaluate a the possibility of clinical trial to assess the risks and benefits of the Recovery Filter in light of substantially higher reported failure rates. Bard then used Dr. Lehmann and Richard Holcomb to perform that assessment. There is no question that this assessment would have been performed in a substantially similar manner regardless of litigation and there were sufficient motivating business reasons for performing it. Bard should not be allowed to manufacture a privilege over a planned and required business activity by simply using in house counsel to outsource the work to "consultants." Thus Bard has failed to establish that the primary purpose of the communication was to obtain or provide legal advice, or that the communication was performed "because of" anticipated litigation. The <i>Phillips</i> court in found Joint Selection No. 26 discussing Dr. Lehman's and Mr Holcombs work regardign the clinical study strategies to not be protected. , <i>Phillips v. C.R. Bard, Inc.</i> , 290, F.R.D. 615, 652-53 (D. Nev. 2013)
Log 2	195	10/28/2005	John McDermott	Mary Minske; TPE-Management Board-DG			Email forwarding filter litigation documents prepared in anticipation of litigation.	Work Product			Bard has failed to establish that these communications were prepared/sent in anticipation of litigation or for trial. Bard has refused to identify who requested the information, who authored the attachments, or provide any further detail about why it was being sent.
Log 2	221	8/29/2005	Shari Allen	Suzanne Carpenter (Litigation Manager)	Robert Carr; Janet Hudnall; Judy Ludwig		Email and attachments requesting legal advice from Suzanne Carpenter concerning MHRA response.	Attorney-Client Privilege; Work Product			Bard's privilege claim should be overruled as Ms. Carpenter is not a lawyer and, therefore, cannot give legal advice. Bard's work produce claims should also be denied as Bard has not established any facts demonstrating that this document email was prepared in anticipation of litigation. Simply making a conclusory statement that something is work product is not sufficient. Further the alleged failure being discussed by the MHRA is perforation. Bard has not established having reasons to anticipate lawsuits regarding this failure mode.

Log 2	244	8/29/2005	Shari Allen	Suzanne Carpenter (Litigation Manager); Robert Carr; Janet Hudnall	Judy Ludwig	Email in response to request from Bard Legal Department for information about Recovery Filter product liability claims.	Attorney-Client Privilege; Work Product	Bard has failed to establish privilege as no lawyers is listed having been asked to or actually have rendered legal advice. The email chain apparently relates to a complaint reported by an employee. Bard has failed to establish that this first communication was made "because of" anticipated litigation. Of note, Bard employees are required to report any adverse event they become aware of, which provides an alternative explanation for the communication.
Log 2	281	3/17/2005	David Ciavarella	Richard Holcomb (Consultant)	Shari Allen; Brian Barry; Charis Campbell; Christopher Gueri	Email and attachments containing information prepared to assist counsel in providing legal advice about Recovery Filter clinical protocol.	Consultant	Bard's December 2004 Health Hazard Evaluation advised that Bard should evaluate a the possibility of clinical trial to assess the risks and benefits of the Recovery Filter in light of substantially higher reported failure rates. Bard then used Dr. Lehmann and Richard Holcomb to perform that assessment. There is no question that this assessment would have been performed in a substantially similar manner regardless of litigation and there were sufficient motivating business reasons for performing it. Bard should not be allowed to manufacture a privilege over a planned and required business activity by simply using in house counsel to outsource the work to "consultants." Thus Bard has failed to establish that the primary purpose of the communication was to obtain or provide legal advice, or that the communication was performed "because of" anticipated litigation. The Phillips court in found Joint Selection No. 26 discussing Dr. Lehman's and Mr Holcombs work regarding the clinical study strategies to not be protected. , Phillips v. C.R. Bard, Inc., 290, F.R.D. 615, 652-53 (D. Nev. 2013)
Log 2	290	1/17/2005	David Ciavarella	Shari Allen; Brian Barry		Email and attachments conveying legal advice of Howard Holstein, Esquire about revised customer letter and FDA talking points provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the primary purpose of these communications were to obtain or provide legal advice. No attorney is listed as a participant of the communications or as an author of the attachments. Further, these communications relate to general business matters such as marketing communications to clients and talking point. These are not traditionally legal instruments are discussed in the <i>Vioxx case</i> . It is unclear to what extent Mr. Holstein was acting as a lawyer (giving advice on the consequences of a proposed course of conduct versus being a consultant on Bard's business matters. For instance, he is listed as a team member on Bard's Remedial Action investigation into the Migration problem.
Log 2	293	12/30/2004	Mary Edwards	Pat Rodewald	Shari Allen	Email and attachments regarding legal advice of Judith Reinsdorf, Esquire and Donna Passero, Esquire about sales communication provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard's claim of attorney-client privilege should be denied as Bard has failed to establish that the communication made for the primary purpose of obtaining legal advice. No lawyer is listed as a party to the communication or as an author of the attachments. Further, a sales communication is a general business matter and certainly is not a traditionally legal instrument once would expect lawyers to comment on.
Log 2	336	10/10/2005	Annette Everett	Richard Bliss (Consultant); Kellee Jones; Gin Schulz; Leigh Toole	Wendy Hayes	Email containing information prepared to assist counsel in providing legal advice about Recovery Filter.	Attorney-Client Privilege	Bard has failed to establish that the primary purpose of this communication was to obtain or provide legal advice. No lawyers as listed as being a party to the communication and any confidentiality was waived by disclosure to a third party consultant. There is also no declaration from anyone in the legal department stating that Richard Bliss was retained to provide consultative services to Bard in anticipation of litigation or that the subject memo was done at the direction of the Law Department. See <i>Phillips</i> order as to Joint Selection 27.
Log 2	339	10/10/2005	Kellee Jones	Richard Bliss (Consultant); Annette Everett; Gin Schulz; Leigh Toole	Wendy Hayes	Email to assist counsel in providing legal advice regarding Recovery Filter.	Attorney-Client Privilege; Work Product	Bard has failed to establish that the primary purpose of this communication was to obtain or provide legal advice. No lawyers as listed as being a party to the communication and any confidentiality was waived by disclosure to a third party consultant. There is no declaration from anyone in the legal department stating that Richard Bliss was retained to provide consultative services to Bard in anticipation of litigation or that the subject memo was done at the direction of the Law Department. See <i>Phillips</i> order as to Joint Selection 27.

Log 2	362	1/26/2005	Kim Gonzales	Micky Graves; Janet Hudnall; Brian Hudson		Email and attachments regarding legal advice of Dara Marshall and DeAnn Goodrich (Paralegal) about Recovery Filter Kit Labels provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Privilege cannot apply as niether party allegedly giving legal advice is an attorney. Bard is not claiming that they are passing information but that they are themselves giving legal advice.
Log 2	403	10/3/2005	Janet Hudnall	Shari Allen	Kevin Shifrin	Email and attachments regarding legal advice of Donna Passero, Esquire about G2 sales force call provided to employees who need the information to perform their job functions at the direction of counsel.	Attorney-Client Privilege	Bard's claim of attorney-client privilege should be denied as Bard has failed to: establish that the communication reveals a solicitation for or rendering of advice from a lawyer, discloses any facts suggesting legal advice was being provided or solicited, or that confidentiality was expected or maintained. The communication does not include legal personnel. Bard has also failed to identify who authored the attachments. Further, the communications do not involve a legal matter. Instead they involve a traditional business matter, promotional and marketing practices. See, <i>Phillips v. C.R. Bard, Inc.</i> , 290, F.R.D. 615, 644, 653-654 (D. Nev. 2013)(finding Joint Selection No. 5 (Sales Communication) and No. 29 (Colleague letter) not privileged). Bard has also failed to identify who authored the attachments.
Log 2	441	8/20/2004	Kim Gonzales	Kellee Jones		Email regarding legal advice of Donna Passero, Esquire about Recovery Filter IFU revisions provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Communication does not reveal a communication made with the primary purpose of obtaining or providing legal advice. The redacted section just reveals that lawyers were consulted but not what was requested or what advice was given.
Log 2	462	4/26/2004	Donna Passero, Esquire	Kellee Jones		Email and attachments regarding legal advice about draft Recovery HHE 2.	Attorney-Client Privilege; Consultant	Bard has failed that to establish that the primary purpose of the communications was to obtain legal advice. Bard was required by FDA regulations and its own procedures to conduct a Health Hazard Analysis. Bard inserted in-house lawyers into the Product Assessment Teams, which explains why the Health Hazard Evaluation are sent to the in-house lawyers for review. When there is a sufficient business reason for the communication to have taken place, like here, Bard should not be allowed to manufacturer privilege by simply adding in-house lawyers to the process.
Log 2	486	4/5/2004	Kellee Jones	Howard Holstein, Esquire	Doug Uelmen	Email and attachments to outside counsel for purposes of seeking legal advice about remedial action plan.	Attorney-Client Privilege	Privilege does not apply as the communication is not seeking legal advice. Mr. Holstein, although a lawyer, was not be asked to give advice as to the legal implications of a potential course of action. Instead, he is listed as a team member on the helping to investigate the migration problem.
Log 2	494	8/15/2005	Kellee Jones	Suzanne Carpenter (Litigation Manager)	Richard Bliss (Consultant); Sabina Downing (Litigation Manager); Christopher Ganser; Cindi Walcott	Email and attachments to Bard Legal Department in response to request for information from the same regarding Recovery Filter reports.	Attorney-Client Privilege	Bard has failed to establish that the email or attachments were made for the primary purpose of obtaining legal advice. No lawyer is listed as being part of the communication or having requested the information. Bard also fails to identify who authored the attachments. There is nothing to suggest that these were not communications regarding normal investigations of adverse events. Further, Bard waived any privilege by disclosing the material to a third party consultant.

Log 2	502	8/16/2005	Christopher Ganser	Suzanne Carpenter (Litigation Manager); Kellee Jones	Richard Bliss (Consultant); Sabina Downing (Litigation Manager); Cindi Walcott	Email to Bard Legal Department providing information in response to request from same for information concerning Recovery Filter reports.	Attorney-Client Privilege	Bard has failed to establish that the email or attachments were made for the primary purpose of obtaining legal advice. No lawyer is listed as being part of the communication or having requested the information. Bard also fails to identify who authored the attachments. There is nothing to suggest that these were not communications regarding normal investigations of adverse events or post-market trending. Indeed, Bard prepared monthly trending summaries of failure data so that management could track the failure rates. These were sent to Mr. Ganser who then shared them with John Weiland and Tim Ring. This email chain is just part of the normal process. Further, Bard waived any privilege by disclosing the material to a third party consultant.
Log 2	522	8/22/2005	Sabina Downing (Litigation Manager)	Kellee Jones	Suzanne Carpenter (Litigation Manager)	Email regarding legal advice about Recovery Filter adverse event reports.	Attorney-Client Privilege	Bard has failed to establish that the email was sent for the primary purpose of obtaining legal advice. No lawyer is listed as being part of the communication or having requested the information. There is nothing to suggest that these were not communications regarding normal investigations of adverse events or post-market trending.
Log 2	583	6/7/2005	Judy Ludwig	Dennis Harris; Walsh	Alison Joe DeJohn	Email regarding document retention related to pending litigation.	Work Product	Bard has failed to establish that the communication was created in anticipation of litigation and would not have been created in substantially similar form otherwise. Bard has not established any facts suggesting that Bard's lawyers requested this action be done or that it was being done to prepare for litigation.
Log 2	741	10/6/2004	Glenn Norton	Kim Gonzales		Email conveying legal advice from Bard Corporate Legal Department (Gary Mitchell) about product IFU changes and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the email was sent for the primary purpose of obtaining legal advice. No lawyer is listed as being part of the communication. Nor is there an explanation as to how the lawyer's advice regarding changes to the IFU has legal importance. Unless the lawyer is discussing proposed changes and identifying potential resulting legal implications, privilege should not apply.
Log 2	756	4/25/2005	Cindi Walcott	Kerry Chunko	Tabitha Ferrin; Brian Hudson; Frank Madia	Email and attachments conveying privileged information about filter testing created in anticipation of litigation and provided to employees who need the information to perform their job functions.	Work Product	Bard has failed to establish that the communication was created in anticipation of litigation and would not have been created in substantially similar form otherwise. Indeed, the employees are the ones that would typically test returned product as part of Bard's general requirement to test all returned product associated with adverse events and/or exemplar products to determine the cause of failures. Bard has not established any facts suggesting that Bard's lawyers requested this action be done or that it was being done to prepare for litigation. See <i>Phillips</i> order discussing Joint Selection 27, which found work product did not apply where there no declaration stating the testing had been ordered by Bard's attorneys.
Log 2	766	5/24/2005	Kellee Jones	Richard Bliss (Consultant); Brian Brown; Wendy Hayes; Judy Ludwig; Cindi Walcott		Email and attachments conveying legal advice of Donna Passero, Esquire about filter document retention and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the email or attachments were made for the primary purpose of obtaining or providing legal advice. No lawyer is listed as being part of the communication and Bard fails to identify the author of the attachments. There are no facts presented that Ms. Passero has actually provided legal advice. This may just be that she is circulating company policies. Further to the extent that any privileged information beyond instructions to preserve evidence was disclosed, the privilege was waived by disclosing the materials to a third party consultant.

Log 2	794	7/28/2004	Cindi Walcott	Robert Carr	Chris Dorvee; Don vonLinden	Email conveying legal advice of Donna Passero, Esquire about testing on Recovery Filters conducted in anticipation of litigation and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product	Bard has failed to establish that the communication was created in anticipation of litigation and would not have been created in substantially similar form otherwise. Bard has also failed to establish that the primary purpose of the communication was to provide or obtain legal advice. No lawyers is listed as being a party to the communication. The employees involved are the ones that would typically test returned product as part of Bard's general requirement to test all returned product associated with adverse events and/or exemplar products to determine the cause of failures. Bard has not established any facts suggesting that Bard's lawyers requested this action be done or that it was being done to prepare for litigation. See <i>Phillips</i> order discussing Joint Selection 27, which found work product did not apply where there no declaration stating the testing had been ordered by Bard's attorneys.
Log 2	797	8/15/2005	Kellee Jones	Suzanne Carpenter (Litigation Manager)	Richard Bliss (Consultant); Sabina Downing (Litigation Manager); Christopher Ganser; Cindi Walcott	Email and attachments regarding legal advice about Recovery Filter Reports.	Attorney-Client Privilege	Bard has failed to establish that the primary purpose of the communication was to obtain or provide legal advice. Notably no lawyers are identified as having been asked for or rendered legal advice or having authored the attachments. Bard also waived any privilege by disclosing the information to a third party consultant, Dr. Bliss.
Log 2	809	7/18/2005	Wendy Hayes	Brian Brown; Mandy Ferrin; Kellee Jones; Judy Ludwig; Stephanie Lyke; Leigh Toole; Cindi Walcott	Richard Bliss (Consultant)	Email regarding legal advice of Suzanne Carpenter (Litigation Manager) about pending litigation provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the communication was made for the primary purpose of obtaining legal advice. First, Ms. Carpenter is not a lawyer and, therefore, cannot give legal advice. Second, Bard has not provided any facts suggesting how the matter being discussed in of legal importance. Finally, any privilege was waived by disclosure to Mr. Bliss.
Log 2	816	10/5/2004	Christopher Ganser	Brian Barry; Mary Edwards	David Ciavarella; Donna Passero, Esquire; Doug Uelmen	Email regarding legal advice about Dear Doctor letter.	Attorney-Client Privilege	Bard has failed to establish that the communication was made for the primary purpose of obtaining legal advice. First, Donna Passero was only copied on the communication. Second, Bard does not explain how an email relating to a dear Dr. Letter indicates the solicitation or provision of legal advice. This is general business matter nto something that is traditionally a legal instrument. The <i>Phillips</i> court determined a strikingly similar document to not be privileged for the same reasons. See, <i>Phillips</i> Order discussing Joint Selection 26.
Log 2	837	11/24/2004	John McDermott	Mary Edwards; Janet Hudnall; Doug Uelmen		Email regarding Recovery complaint investigation in preparation of litigation.	Work Product	Bard has failed to establish that the communication was created in anticipation of litigation and would not have been created in substantially similar form otherwise. There is nothing to suggest that this was not part of Bard's general business obligation to investigate adverse events. Further, Bard has not provides any facts indicating that this was ordered or done at the request of Bard's lawyers.
Log 2	859	8/18/2004	Brian Barry	Robert Carr; Doug Uelmen	Shari Allen; David Ciavarella; Mary Edwards; Christopher Ganser; Kim Gonzales; Janet Hudnall; Karen Hutchison; Pete Palermo; Donna Passero, Esquire	Email regarding legal advice about Recovery Filter IFU revisions.	Attorney-Client Privilege	Bard has failed to establish that the redacted communications were made for the purpose of obtaining legal advice. The email just relates to a team effort to review and comment on a proposed IFU. This is a non-legal function, which is certainly supported by the group effort. Further, given the wide distribution confidentiality was not maintained or expected.
Log 2	1023	5/17/2004	John Kaufman	Janet Hudnall		Email reflecting legal advice of Stephen Long, Esquire about medical record review provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product	Bard has failed to establish that the communication was made for the primary purpose of securing or providing legal advice. To the extent that attorney-client privilege did exist, it was waived by disclosure. Further, Bard has failed to establish that the communication was created in anticipation of litigation and would not have been created in substantially similar form otherwise. The only factual information presented is that between Dr. Kaufman (a third party doctor) and Bard's Marketing Manager.

Log 2	1220	9/13/2005	Charis Campbell	John Kaufman		Email and attachments conveying legal advice of Thomas Klein, Esquire about contract documents and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege			Bard has failed to establish that the communication was made for primary purpose of securing legal advice. No lawyers are listed as participants to the communication. Further no explanation is given as to how this communication reveals legal advice, or who authored the attachments. Even if privilege did exist, it was waived by disclosure to Dr. Kaufman.
Log 3	57	9/2/2010	Cindi Walcott	Bret Baird	Brian Hudson; Bill Little; John Van Vleet	Email requesting and reflecting legal advice of Greg Dadika, Esquire about a patient inquiry provided to employees who need the information to perform their job functions.	Attorney-Client Privilege			Log 3, Nos. 57, 127-130, 135 and 136 are all similar. This is a long email chain that begins on September 1, 2010 with a communication from a patient with a G2 Filter asking whether the risk of failure goes up the longer these devices are left in place. He asks if he should worry and mentions he cannot get an answer from his doctor. There are then a series of internal emails that eventually lead to an in-house lawyer being asked to comment on how Bard should respond. To the extent that the in-house lawyer is merely parroting Bard's position on what to tell or not tell such patients, this is not legal advice. Further, given his response is likely being taken and shared with the public, the communication is not meant to be confidential.
Log 3	119	9/17/2010	Gin Schulz	Jim Beasley	Abthilal Raji-Kubba	Email and attachments regarding legal advice of Brandee Kowalzyk, Esquire, Gina Dunsmuir, Esquire and Brian Leddin, Esquire about filter physician letter provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product			Bard fails to establish that the purpose of these communications was to obtain legal advice and that confidentiality was maintained. First, no lawyers are listed as being a party to the communication. Second, Bard fails to explain how commenting on marketing and promotional letter to doctors implicates legal advice. Further, there is no explanation for how discussing a letter to doctors was being done because of anticipated litigation and would not have been created in a substantially similar form but for litigation.
Log 3	126	9/29/2010	Sandy Kerns	Cindi Walcott		Email reflecting legal advice of Sabina Downing (Litigation Manager) about filter adverse event provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product			Bard's privilege claim should be overruled as Ms. Downing is not a lawyer and, therefore, cannot give legal advice. Bard's work product claim should also be denied as Bard has not established any facts demonstrating that this document email was prepared in anticipation of litigation. Simply making a conclusory statement that something is work product is not sufficient. Further, given that Bard had a separate and distinct business obligation to investigate all adverse events and take corrective action if necessary, Bard cannot establish that these communications would not have been created in a substantially similar form but for anticipated litigation.
Log 3	127	9/2/2010	Cindi Walcott	Bret Baird	Bill Little; John Van Vleet; Brian Hudson	Portion of email regarding legal advice of Greg Dadika, Esquire regarding patient complaint and potential legal claimant and provided to employees who need the information to perform their job functions and sent in anticipation of litigation.	Attorney-Client Privilege; Work Product	BPVEFILTE R-01-00215368	BPVEFILTE R-01-00215374	Log 3, Nos. 57, 127-130, 135 and 136 are all similar. This is a long email chain that begins on September 1, 2010 with a communication from a patient with a G2 Filter asking whether the risk of failure goes up the longer these devices are left in place. He asks if he should worry and mentions he cannot get an answer from his doctor. There are then a series of internal emails that eventually lead to an in-house lawyer being asked to comment on how Bard should respond. To the extent that the in-house lawyer is merely parroting Bard's position on what to tell or not tell such patients, this is not legal advice. Further, given his response is likely being taken and shared with the public, the communication is not meant to be confidential.

Log 3	128	9/2/2010	Cindi Walcott	Bret Baird	Bill Little; John Van Vleet; Brian Hudson	Portion of email regarding legal advice of Greg Dadika, Esquire regarding patient complaint and potential legal claimant and provided to employees who need the information to perform their job functions and sent in anticipation of litigation.	Attorney-Client Privilege; Work Product	BPVEFILTE R-01-00215375	BPVEFILTE R-01-00215380	Log 3, Nos. 57, 127-130, 135 and 136 are all similar. This is a long email chain that begins on September 1, 2010 with a communication from a patient with a G2 Filter asking whether the risk of failure goes up the longer these devices are left in place. He asks if he should worry and mentions he cannot get an answer from his doctor. There are then a series of internal emails that eventually lead to an in-house lawyer being asked to comment on how Bard should respond. To the extent that the in-house lawyer is merely parroting Bard's position on what to tell or not tell such patients, this is not legal advice. Further, given his response is likely being taken and shared with the public, the communication is not meant to be confidential.
Log 3	129	9/2/2010	Cindi Walcott	Bret Baird	Bill Little; John Van Vleet; Brian Hudson	Portion of email regarding legal advice of Greg Dadika, Esquire regarding patient complaint and potential legal claimant and provided to employees who need the information to perform their job functions and sent in anticipation of litigation.	Attorney-Client Privilege; Work Product	BPVEFILTE R-01-00215381	BPVEFILTE R-01-00215385	Log 3, Nos. 57, 127-130, 135 and 136 are all similar. This is a long email chain that begins on September 1, 2010 with a communication from a patient with a G2 Filter asking whether the risk of failure goes up the longer these devices are left in place. He asks if he should worry and mentions he cannot get an answer from his doctor. There are then a series of internal emails that eventually lead to an in-house lawyer being asked to comment on how Bard should respond. To the extent that the in-house lawyer is merely parroting Bard's position on what to tell or not tell such patients, this is not legal advice. Further, given his response is likely being taken and shared with the public, the communication is not meant to be confidential.
Log 3	130	9/2/2010	Cindi Walcott	Debra Griffith		Portion of email regarding legal advice of Greg Dadika, Esquire regarding patient complaint and potential legal claimant and provided to employees who need the information to perform their job functions and sent in anticipation of litigation.	Attorney-Client Privilege; Work Product	BPVEFILTE R-01-00215386	BPVEFILTE R-01-00215388	Log 3, Nos. 57, 127-130, 135 and 136 are all similar. This is a long email chain that begins on September 1, 2010 with a communication from a patient with a G2 Filter asking whether the risk of failure goes up the longer these devices are left in place. He asks if he should worry and mentions he cannot get an answer from his doctor. There are then a series of internal emails that eventually lead to an in-house lawyer being asked to comment on how Bard should respond. To the extent that the in-house lawyer is merely parroting Bard's position on what to tell or not tell such patients, this is not legal advice. Further, given his response is likely being taken and shared with the public, the communication is not meant to be confidential.
Log 3	131	9/30/2010	Sabina Downing (Litigation Manager)	Cindi Walcott		Email regarding filter complaint created in anticipation of litigation.	Work Product			Bard has failed to establish that under totality of circumstances the document would not have been created in a substantially similar form but for the prospect of litigation. Bard has an independent business duty to investigate all adverse events to determine how the device failed, if someone was else was at fault, and to determine what, if any corrective action, is necessary to prevent recurrence.
Log 3	135	9/2/2010	Cindi Walcott	Bret Baird	Bill Little; John Van Vleet; Brian Hudson	Portion of email regarding legal advice of Greg Dadika, Esquire regarding patient complaint and potential legal claimant and provided to employees who need the information to perform their job functions and sent in anticipation of litigation.	Attorney-Client Privilege; Work Product	BPVEFILTE R-01-00215396	BPVEFILTE R-01-00215401	Log 3, Nos. 57, 127-130, 135 and 136 are all similar. This is a long email chain that begins on September 1, 2010 with a communication from a patient with a G2 Filter asking whether the risk of failure goes up the longer these devices are left in place. He asks if he should worry and mentions he cannot get an answer from his doctor. There are then a series of internal emails that eventually lead to an in-house lawyer being asked to comment on how Bard should respond. To the extent that the in-house lawyer is merely parroting Bard's position on what to tell or not tell such patients, this is not legal advice. Further, given his response is likely being taken and shared with the public, the communication is not meant to be confidential.

Log 3	136	9/2/2010	Cindi Walcott	Debra Griffith		Email regarding legal advice of Greg Dadika, Esquire regarding patient complaint and potential legal claimant and provided to employees who need th information to perform their job functions and sent in anticipation of litigation.	Attorney-Client Privilege; Work Product	Log 3, Nos. 57, 127-130, 135 and 136 are all similar. This is a long email chain that begins on September 1, 2010 with a communication from a patient with a G2 Filter asking whether the risk of failure goes up the longer these devices are left in place. He asks if he should worry and mentions he cannot get an answer from his doctor. There are then a series of internal emails that eventually lead to an in-house lawyer being asked to comment on how Bard should respond. To the extent that the in-house lawyer is merely parroting Bard's position on what to tell or not tell such patients, this is not legal advice. Further, given his response is likely being taken and shared with the public, the communication is not meant to be confidential.
Log 3	175	10/12/2006	John McDermott	Shari Allen; Joe DeJohn; Janet Hudnall; Gin Schulz	Mary Minske; Kevin Shifrin	Email reflecting legal advice of Judith Reinsdorf, Esquire about a communication plan provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	<p>Entries from Log 3, Nos. 175, 505.01, 519, 520.01, 521, 523 and 3804 all involve the same disputed information. This is an email chain that begins with John McDermott emailing Judith Reinsdorf (Vice President, Secretary, and General Counsel of C.R. Bard) on October 10, 2006 and copying Brian Barry, Dr. Ciavarella, Christopher Ganser, Shari Allen, Janet Hudnall, and Gin Schulz with the subject line "G2", as in G2 Filter. The email apparently contained an attached "action and communication" plan prepared by Mr. McDermott. Ms. Reinsdorf replies on October 12, to Mr. McDermott and copies John Weiland, and Brian Barry. She notes that she has reviewed Mr. McDermott's action and communication plan with Brian Barry and John Weiland and they are in agreement on a number of issues regarding the plan, which she goes on to identify. The entire email is the forwarded four more times and is seen by multiple different employees, including for example Cindi Walcott (Field Assurance Manager), who is responsible for investigating adverse events.</p> <p>Bard's privilege claim should be denied as it has failed to establish that the communication was made for the primary purpose of soliciting legal advice or that confidentiality was expected or maintained. First, there is nothing that appears to be of legal significance to the communications. This is simply a marketing communication, which is certainly not the type of traditional legal document discussed in the Vioxx case. Further, while Ms. Reinsdorf is a lawyer, she also held the positions of Vice President and Secretary for C.R. Bard. Thus, she was not necessarily acting in her role as a lawyer. The initial email was also sent out for simultaneous review and comment to other non-lawyers. Indeed, Ms. Reinsdorf makes it clear that she did in fact review the plan with other non-lawyers and that her suggestions were reached jointly with the non-lawyers. This strongly indicated that the primary purpose was business related. Finally, Bard has not established why the numerous employees who were provided with this email chain needed it to fulfill the purpose for why the lawyer was consulted.</p>
Log 3	224	9/7/2006	John McDermott	Janet Hudnall	Shari Allen; Joe DeJohn; Kevin Shifrin	Email and attachment reflecting legal advice of Judith Reinsdorf, Esquire and Donna Passero, Esquire about product communication plan to sales force provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the primary purpose of the communications was to obtain or provide legal advice. Bard has not established that any lawyer authored the attachments or in what way did lawyers provide "legal" advice about the proposed sales force communication. These are not traditionally legal documents, such that edits and commentary would be protected.

Log 3	264	11/26/2007	Brett Enlow	Janet Hudnall		Email and attachments reflecting legal advice of Gina Dunsmuir, Esquire about revisions to Sales Force Guidance provided to employees who need the information to perform their job functions.	Attorney-Client Privilege			Bard has failed to establish that primary purpose of communication was seeking or providing legal advice or that confidentiality was maintained. This is a communication between non-lawyers regarding a business activity and not legal advice. As noted by the magistrate judge in Phillips, grammatical, editorial, and word choice comments are not legal advice.
Log 3	317	1/14/2008	Ella Martin	Genevieve Balutowski; Janet Hudnall		Email and attachments reflecting legal advice from Brian Leddin, Esquire, about product study abstract provided to employees who need the information to perform their job functions.	Attorney-Client Privilege			Bard has failed to establish that the primary purpose of the communications was to obtain or provide legal advice. No lawyers are listed as a party to the communication and this involves a non-legal matter - a study abstract. As discussed in Vioxx, technical documents and medical studies are not deemed a traditionally legal instrument and edits and commentary on these materials will not be deemed privileged.
Log 3	326	5/5/2006	Khoi Ta, Esquire	John Kaufman	Len DeCant; Janet Hudnall; David Laub, Esquire	Email and attachments conveying legal advice of Khoi Ta, Esquire regarding product patent application.	Attorney-Client Privilege			Bard has failed to establish that the primary purpose of this communication was obtain or provide legal advice. There is no evidence that Dr. Kaufman was retained to assist with the preparation of the patent or that he helped in interpret any already privileged material. Rather, Bard seems to have simply sent him a copy of the application and suggested he be listed as a patent holder. Certain materials produced in this litigation suggest that Bard tried to funnel money to leading physicians by listing them as patent holders. To the extent any privilege existed, it was waived by disclosing the documents to Dr. Kaufman.
Log 3	334	3/24/2006	Janet Hudnall	Gin Schulz		Email reflecting legal advice of Brian Leddin, Esquire about phone call from customer and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege			This entry consists of an email chain regarding a hospital risk manager calling about two adverse events, including death case, and about whether Bard reported these to FDA. Bard has failed to establish that the rdacted communications reveal a request for or rendering of legal advice. The subject matter invovled seems to be a simply business matter, where the events reported or not. Further, to the extent that the in-house lawyer is simply parroting the company approved message, that certainly would not be privileged. Further to the extent that anything said by the lawyer was shared with the risk manager, confidentiality would not exist.
Log 3	335	4/21/2006	Janet Hudnall	John Kaufman		Email and attachments reflecting legal advice of Khoi Ta, Esquire about product application and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege			Bard has failed to establish that the primary purpose of this communication was obtain or provide legal advice. There is no evidence that Dr. Kaufman was retained to assist with the preparation of the patent or that he helped in interpret any already privileged material. Rather, Bard seems to have simply sent him a copy of the application and suggested he be listed as a patent holder. Certain materials produced in this litigation suggest that Bard tried to funnel money to leading physicians by listing them as patent holders. To the extent any privilege existed, it was waived by disclosing the documents to Dr. Kaufman.
Log 3	336	5/11/2006	Melinda Duensing	Janet Hudnall; Charlie Simpson	Leigh Toole	Email reflecting legal advice of Bard Corporate Legal Department about product inventory and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	BPVEFILTE R-01-00002594	BPVEFILTE R-01-00002594	This entry consists of an email chain regarding a hospital risk manager calling about two adverse events, including death case, and about whether Bard reported these to FDA. Bard has failed to establish that the rdacted communications reveal a request for or rendering of legal advice. The subject matter invovled seems to be a simply business matter, where the events reported or not. Further, to the extent that the in-house lawyer is simply parroting the company approved message, that certainly would not be privileged. Further to the extent that anything said by the lawyer was shared with the risk manager, confidentiality would not exist.

Log 3	347	1/13/2006	Janet Hudnall	John Kaufman	Email and attachments reflecting legal advice of Khoi Ta, Esquire and outside trademark counsel about patents provided to employees who need the information to perform their job functions.	Attorney-Client Privilege			This documents was reviewed during meet and confer efforts. Defendants have failed to explain how a simple picture being excahnged between Dr. Kaufman and Bard's marketing manager could possible evidence legal advice having been provided or requested. Even if it had, Bard has failed to establish that there was an attorney-client relationship between Dr. Kaufman and any of Bard's lawyers. Thus, any privilege was waived.	
Log 3	423	11/26/2007	Janet Hudnall	Brett Enlow; John Van Vleet	Email and attachments reflecting legal advice of Gina Dunsmuir, Esquire about revisions to sales force guidance provided to employees who need the information to perform their job functions.	Attorney-Client Privilege			Same or similiar to Log 3, No. 264. Bard has failed to establish that primary purpose of communication was seeking or providing legal advice or that confidentiality was maintained. This is a communication between non-lawyers regarding a business activity and not legal advice. As noted by the magistrate judge in Phillips, grammatical, editorial, and word choice comments are not legal advice.	
Log 3	505.01	10/12/2006	John McDermott	Gin Schulz; Janet Hudnall; Shari Allen; Minske Joe DeJohn	Kevin Shifrin; Mary	Email requesting and reflecting legal advice from Judith Reinsdorf, Esquire regarding sales force communication.	Attorney-Client Privilege	BPVEFILTE R-01-00002742	BPVEFILTE R-01-00002744	<p>Entries from Log 3, Nos. 175, 505.01, 519, 520.01, 521, 523 and 3804 all invovle the same disputed information. This is an email chain that begins with John McDermott emailing Judith Reinsdorf (Vice President, Secretary, and General Counsel of C.R. Bard) on October 10, 2006 and copying Brian Barry, Dr. Ciavarella, Christopher Ganser, Shari Allen, Janet Hudnall, and Gin Schulz with the subject line "G2", as in G2 Filter. The email apparently contained an attached "action and communication" plan prepared by Mr. McDermott. Ms. Reinsdorf replies on October 12, to Mr. McDermott and copies John Weiland, and Brian Barry. She notes that she has reviewed Mr. McDermott's action and communication plan with Brian Barry and John Weiland and they are in agreement on a number of issues regarding the plan, which she goes on to identify. The entire email is the forwarded four more times and is seen by multiple different employees, including for example Cindi Walcott (Field Assurance Manager), who is responsible for investigating adverse events.</p> <p>Bard's privilege claim should be denied as it has failed to establish that the communication was made for the primary purpose of soliciting legal advice or that confidentiality was expected or maintained. First, there is nothing that appears to be of legal significance to the communications. This is simply a marketing communication, which is certainly not the type of traditional legal document discussed in the Vioxx case. Further, while Ms. Reinsdorf is a lawyer, she also held the positions of Vice President and Secretary for C.R. Bard. Thus, she was not necessarily acting in her role as a lawyer. The initial email was also sent out for simultaneous review and comment to other non-lawyers. Indeed, Ms. Reinsdorf makes it clear that she did in fact review the plan with other non-lawyers and that her suggestions were reached jointly with the non-lawyers. This strongly indicated that the primary purpose was business related. Finally, Bard has not established why the numerous employees who were provided with this email chain needed it to fulfill the purpose for why the lawyer was consulted.</p>

Log 3	519	10/12/2006	John McDermott	Shari Allen; Joe DeJohn; Janet Hudnall; Gin Schulz	Mary Minske; Kevin Shifrin	Email requesting and reflecting legal advice of Judith Reinsdorf, Esquire about a communication plan provided to employees who need the information to perform their job functions.	Attorney-Client Privilege			<p>Entries from Log 3, Nos. 175, 505.01, 519, 520.01, 521, 523 and 3804 all involve the same disputed information. This is an email chain that begins with John McDermott emailing Judith Reinsdorf (Vice President, Secretary, and General Counsel of C.R. Bard) on October 10, 2006 and copying Brian Barry, Dr. Ciavarella, Christopher Ganser, Shari Allen, Janet Hudnall, and Gin Schulz with the subject line "G2", as in G2 Filter. The email apparently contained an attached "action and communication" plan prepared by Mr. McDermott. Ms. Reinsdorf replies on October 12, to Mr. McDermott and copies John Weiland, and Brian Barry. She notes that she has reviewed Mr. McDermott's action and communication plan with Brian Barry and John Weiland and they are in agreement on a number of issues regarding the plan, which she goes on to identify. The entire email is the forwarded four more times and is seen by multiple different employees, including for example Cindi Walcott (Field Assurance Manager), who is responsible for investigating adverse events.</p> <p>Bard's privilege claim should be denied as it has failed to establish that the communication was made for the primary purpose of soliciting legal advice or that confidentiality was expected or maintained. First, there is nothing that appears to be of legal significance to the communications. This is simply a marketing communication, which is certainly not the type of traditional legal document discussed in the Vioxx case. Further, while Ms. Reinsdorf is a lawyer, she also held the positions of Vice President and Secretary for C.R. Bard. Thus, she was not necessarily acting in her role as a lawyer. The initial email was also sent out for simultaneous review and comment to other non-lawyers. Indeed, Ms. Reinsdorf makes it clear that she did in fact review the plan with other non-lawyers and that her suggestions were reached jointly with the non-lawyers. This strongly indicated that the primary purpose was business related. Finally, Bard has not established why the numerous employees who were provided with this email chain needed it to fulfill the purpose for why the lawyer was consulted.</p>
Log 3	520.01	10/12/2006	John McDermott	Gin Schulz; Janet Hudnall; Shari Allen; Joe DeJohn	Kevin Shifrin; Mary Minske	Email requesting and reflecting legal advice from Judith Reinsdorf, Esquire regarding sales force communication.	Attorney-Client Privilege	BPVEFILTE R-01- 00002766	BPVEFILTE R-01- 00002768	<p>Entries from Log 3, Nos. 175, 505.01, 519, 520.01, 521, 523 and 3804 all involve the same disputed information. This is an email chain that begins with John McDermott emailing Judith Reinsdorf (Vice President, Secretary, and General Counsel of C.R. Bard) on October 10, 2006 and copying Brian Barry, Dr. Ciavarella, Christopher Ganser, Shari Allen, Janet Hudnall, and Gin Schulz with the subject line "G2", as in G2 Filter. The email apparently contained an attached "action and communication" plan prepared by Mr. McDermott. Ms. Reinsdorf replies on October 12, to Mr. McDermott and copies John Weiland, and Brian Barry. She notes that she has reviewed Mr. McDermott's action and communication plan with Brian Barry and John Weiland and they are in agreement on a number of issues regarding the plan, which she goes on to identify. The entire email is the forwarded four more times and is seen by multiple different employees, including for example Cindi Walcott (Field Assurance Manager), who is responsible for investigating adverse events.</p> <p>Bard's privilege claim should be denied as it has failed to establish that the communication was made for the primary purpose of soliciting legal advice or that confidentiality was expected or maintained. First, there is nothing that appears to be of legal significance to the communications. This is simply a marketing communication, which is certainly not the type of traditional legal document discussed in the Vioxx case. Further, while Ms. Reinsdorf is a lawyer, she also held the positions of Vice President and Secretary for C.R. Bard. Thus, she was not necessarily acting in her role as a lawyer. The initial email was also sent out for simultaneous review and comment to other non-lawyers. Indeed, Ms. Reinsdorf makes it clear that she did in fact review the plan with other non-lawyers and that her suggestions were reached jointly with the non-lawyers. This strongly indicated that the primary purpose was business related. Finally, Bard has not established why the numerous employees who were provided with this email chain needed it to fulfill the purpose for why the lawyer was consulted.</p>

Log 3	521	10/12/2006	John McDermott	Shari Allen; Janet Hudnall; Gin Schulz		Emails requesting and reflecting legal advice of Judith Reinsdorf, Esquire about a communication plan provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Entries from Log 3, Nos. 175, 505.01, 519, 520.01, 521, 523 and 3804 all involve the same disputed information. This is an email chain that begins with John McDermott emailing Judith Reinsdorf (Vice President, Secretary, and General Counsel of C.R. Bard) on October 10, 2006 and copying Brian Barry, Dr. Ciavarella, Christopher Ganser, Shari Allen, Janet Hudnall, and Gin Schulz with the subject line "G2", as in G2 Filter. The email apparently contained an attached "action and communication" plan prepared by Mr. McDermott. Ms. Reinsdorf replies on October 12, to Mr. McDermott and copies John Weiland, and Brian Barry. She notes that she has reviewed Mr. McDermott's action and communication plan with Brian Barry and John Weiland and they are in agreement on a number of issues regarding the plan, which she goes on to identify. The entire email is the forwarded four more times and is seen by multiple different employees, including for example Cindi Walcott (Field Assurance Manager), who is responsible for investigating adverse events. Bard's privilege claim should be denied as it has failed to establish that the communication was made for the primary purpose of soliciting legal advice or that confidentiality was expected or maintained. First, there is nothing that appears to be of legal significance to the communications. This is simply a marketing communication, which is certainly not the type of traditional legal document discussed in the Vioxx case. Further, while Ms. Reinsdorf is a lawyer, she also held the positions of Vice President and Secretary for C.R. Bard. Thus, she was not necessarily acting in her role as a lawyer. The initial email was also sent out for simultaneous review and comment to other non-lawyers. Indeed, Ms. Reinsdorf makes it clear that she did in fact review the plan with other non-lawyers and that her suggestions were reached jointly with the non-lawyers. This strongly indicated that the primary purpose was business related. Finally, Bard has not established why the numerous employees who were provided with this email chain needed it to fulfill the purpose for why the lawyer was consulted.
Log 3	522	5/5/2006	Khoi Ta, Esquire	John Kaufman	Len DeCant; Janet Hudnall; David Laub, Esquire	Email and attachments regarding legal advice about a Consultant agreement.	Attorney-Client Privilege	Bard has failed to establish that the primary purpose of the agreement was to provide or obtain legal advice. Bard fails to identify what lawyer, if any, allegedly provided legal advice. It's doubtful that Mr. Ta did, as he is patent attorney.

Log 3	523	10/12/2006	Janet Hudnall	Shari Allen; Joe DeJohn; John McDermott; Gin Schulz	Mary Minske; Kevin Shifrin	Email and attachments requesting and reflecting legal advice of Judith Reinsdorf, Esquire about product sales communication provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	<p>Entries from Log 3, Nos. 175, 505.01, 519, 520.01, 521, 523 and 3804 all involve the same disputed information. This is an email chain that begins with John McDermott emailing Judith Reinsdorf (Vice President, Secretary, and General Counsel of C.R. Bard) on October 10, 2006 and copying Brian Barry, Dr. Ciavarella, Christopher Ganser, Shari Allen, Janet Hudnall, and Gin Schulz with the subject line "G2", as in G2 Filter. The email apparently contained an attached "action and communication" plan prepared by Mr. McDermott. Ms. Reinsdorf replies on October 12, to Mr. McDermott and copies John Weiland, and Brian Barry. She notes that she has reviewed Mr. McDermott's action and communication plan with Brian Barry and John Weiland and they are in agreement on a number of issues regarding the plan, which she goes on to identify. The entire email is the forwarded four more times and is seen by multiple different employees, including for example Cindi Walcott (Field Assurance Manager), who is responsible for investigating adverse events.</p> <p>Bard's privilege claim should be denied as it has failed to establish that the communication was made for the primary purpose of soliciting legal advice or that confidentiality was expected or maintained. First, there is nothing that appears to be of legal significance to the communications. This is simply a marketing communication, which is certainly not the type of traditional legal document discussed in the Vioxx case. Further, while Ms. Reinsdorf is a lawyer, she also held the positions of Vice President and Secretary for C.R. Bard. Thus, she was not necessarily acting in her role as a lawyer. The initial email was also sent out for simultaneous review and comment to other non-lawyers. Indeed, Ms. Reinsdorf makes it clear that she did in fact review the plan with other non-lawyers and that her suggestions were reached jointly with the non-lawyers. This strongly indicated that the primary purpose was business related. Finally, Bard has not established why the numerous employees who were provided with this email chain needed it to fulfill the purpose for why the lawyer was consulted.</p>
Log 3	528	10/17/2006	Janet Hudnall	Bob Cortezzi		Email reflecting legal advice of Brian Leddin, Esquire about a customer inquiry provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	<p>This entry consists of an email chain starting with a customer inquiry making a request for safety data. He requested data to allow a calculation of the reported fracture rate. The email is bounced around internally and eventually in-house counsel makes a recommendation, which is redacted. Bard has failed to establish that this is legal advice. To the extent that in-house counsel is just parroting the company's procedure or approved message, then this is certainly not legal advice. Further to the extent his messaging was then used to respond to the consumer, confidentiality was waived.</p>
Log 3	1096	8/14/2006	Kendra Sinclair-McGee	Cindi Walcott		Email reflecting legal advice of Suzanne Carpenter (Litigation Manager) about potential litigation file created in anticipation of and furtherance of litigation and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product	<p>Bard has failed to establish that primary purpose of communication was seeking or providing legal advice, that confidentiality was maintained, or that under totality of circumstances it would not have been created in a substantially similar form but for the prospect of litigation. Indeed, there is no indication that any lawyer was involved in the communication. Non-lawyers cannot give legal advice.</p>
Log 3	1413	6/4/2007	Robert Carr	Thomas Conniff, Esquire	Luke Harada; Carl Rickenbaugh	Email and attachments requesting legal advice from attorney Thomas Conniff regarding prototypes sent to employees who need the information to perform their job functions.	Attorney-Client Privilege	<p>Bard has failed to establish how this communication reveals and/or seeks legal advice. Further, confidentiality is raised as Mr. Ravenscroft is not an employee of Bard, nor did not have an attorney-client relationship with Bard.</p>

Log 3	1421	11/30/2007	Dennis Salzmann	Genevieve Balutowski		Email and attachments regarding legal advice of Gina Dunsmuir, Esquire about sales force guidance provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard's claim of attorney-client privilege should be denied as Bard has failed to: establish that the communication reveals a solicitation for or rendering of advice from a lawyer, discloses any facts suggesting legal advice was being provided or solicited, or that confidentiality was expected or maintained. The listed communication does not include attorneys and no attorney is listed as an author of the attachments. Further, the communications do not involve a legal matter. Instead they involve a traditional business matter, promotional and marketing practices. See, <i>Phillips v. C.R. Bard, Inc.</i> , 290, F.R.D. 615, 644, 653-654 (D. Nev. 2013)(finding Joint Selection No. 5 (Sales Communication) and No. 29 (Colleague letter) not privileged). Bard has also failed to identify who authored the attachments.
Log 3	1486	2/5/2009	Genevieve Balutowski	Bret Baird; Robert Carr; Jon Conaway; Mike Randall; John Reviere		Email and attachments reflecting request for legal advice of Gina Dunsmuir, Esquire and Greg Dadika, Esquire about product risk review provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	This entry contains an email chain that has now been produced and an attachment that is still being withheld. The email chain begins with an email from Mike Randall dated February 5, 2009 to Brett Baird (Marketing Manager), Genevieve Balutowski (Regulatory Affairs Specialist), Jon Conaway (Quality Assurance), John Reviere (Director, Clinical Affairs), and Robert Carr with a subject line entitled "G2 Expand Completed Action item Summary." In the Body he requests review and comment on the draft so he can send it out "today". On the same day he responds to the same people that the summary has been updated based on their feedback. Jon Conaway then sends an email with the attached "G2 Expand Meeting Action Item Summary Final" to gin Schulz, Mike Randall and Robin Smithson requesting to speak ASAP. Bard claims the attachment reveals legal advice about a product risk review. Bard has failed to establish any facts suggesting the attachment was prepared for the primary purpose of soliciting legal advice. There are no lawyers involved in the email chain or listed as authors of the attachments. Further, the attachment seems to relate to a marketing and/or business plan relating the the G2 Filter. There does not appear to be anything indicating legal significance to the document. The emails also clearly indicates that the attachment was prepared by non-lawyers.
Log 3	1569	12/6/2006	John McDermott	Carl Rickenbaugh	Robert Carr; Janet Hudnall	Email reflecting request for and legal advice of Thomas Conniff, Esquire about acquisition of new filter technology provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	This is basically the same as entry as Log 3, No. 1697. This is an email chain involving Bard's negotiations to buy an safer IVC filter design from Phase One Medical. The first email sent by Carl Rickenbaugh on December 5, 2006 to Thomas Connif (outside counsel) and Luke Harada (VP Business Development) and copied to Robert Carr, John McDermott (BPV President), Kevin Shifrin (VP Marketing), Bob Mellen (VP Planning and Business Development), Janet Hudnall (Marketing Manager), and Bill Krueger (Finance Manager) with a subject line "Phase One Term Sheet." He then goes on to discuss his negotiations with Phase One and his advice for moving forward. Importantly, he does not request any legal advice. Bard has now produced the email but has redacted significant parts of Mr. Rickenbaugh's advice and planning. Bard privilege redacted should be overruled as Bard has not established that this communication as made for the primary purpose of requesting legal advice. Indeed, the author is simply providing his own advice for moving forward. The email simply reflect a business negotiation being done by a non-lawyer. Further, Bard fails to explain why people such as to why the marketing employees would need sensitive legal information.
Log 3	1685	3/1/2007	Luke Harada	Robert Carr	Thomas Conniff, Esquire; Peter Pirsch; Carl Rickenbaugh	Email and attachments reflecting legal advice about a draft development agreement.	Attorney-Client Privilege	The email and attachment is simply a business letter notifying Phase One Medical of Bard's decision and the reason why. (See Log 3, Nos. 1569 and 1697 regarding Phase One Neogtiations). Bard has failed to establish that the primary purpose of the communication was to obtain or give legal advice. A letter simply informing another party as the results of a negotiation and the reasons why, is not legal advice.
Log 3	1694	6/8/2007	Carl Rickenbaugh	Robert Carr; Thomas Conniff, Esquire; Robert Coyne, Esquire; Luke Harada; Kevin Kramer, Esquire		Email and attachments regarding legal advice about a negotiation letter for potential acquisition.	Attorney-Client Privilege	This is another communicationr egarding Bard's negotiation to buy another safer alternative design filter from Phase One Medical. Bard privilege claim fails as the primary purpose of the communication was not to obtain or provide legal advice. As seen in Log 3, Nos. 1569 and 1697, Carl Rickenbaugh was the one doing the negotiating and providing advice and planning on how to move forward. There is no suggestion that he was requesting legal advice from these lawyers.

Log 3	1697	12/6/2006	Robert Carr	John McDermott; Carl Rickenbaugh	Janet Hudnall	Email regarding legal advice of Thomas Conniff, Esquire about a draft term sheet provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	This is basically the same as entry 1569 from log 3. This is an email chain involving Bard's negotiations to buy an safer IVC filter design from Phase One Medical. The first email sent by Carl Rickenbaugh on December 5, 2006 to Thomas Conniff (outside counsel) and Luke Harada (VP Business Development) and copied to Robert Carr, John McDermott (BPV President), Kevin Shifrin (VP Marketing), Bob Mellen (VP Planning and Business Development), Janet Hudnall (Marketing Manager), and Bill Krueger (Finance Manager) with a subject line "Phase One Term Sheet." He then goes on to discuss his negotiations with Phase One and his advice for moving forward. Importantly, he does not request any legal advice. Bard has now produced the email but has redacted significant parts of Mr. Rickenbaugh's advice and planning. Bard privilege redacted should be overruled as Bard has not established that this communication as made for the primary purpose of requesting legal advice. Indeed, the author is simply providing his own advice for moving forward. The email simply reflect a business negotiation being done by a non-lawyer. Further, Bard fails to explain why people such as to why the marketing employees would need sensitive legal information.
Log 3	1763	5/15/2007	Sue Hohmann	Michele Carter; Gina Dunsmuir, Esquire; Dennis Salzmman	Kevin Shifrin	Email and attachments requesting legal advice about Tradeshow & Publication Matrices.	Attorney-Client Privilege	This is an email from Sue Hohmann (Manager of Marketing Communications) dated May 15, 2007 to Dennis Salzmman (Regulatory Affairs Manager), Gina Dunsmuir (in-house counsel), Michele Carter (Marketing Manger), and copied to Kevin Shifrin (VP of Marketing). The subject line is "TRADESHOW & PUBLICATIONS MATRICES." Ms. Hohmann writes "[a]ttached is an update of the matrices showing the current tradeshow and publications...." Bard has now produced the email but is still withholding the attachment. Bard has failed, however, to establish that the primary purpose of these documents was to seek legal advice. First, the documents do not relate to a legal issue. They are simply a list of tradeshow and publications that Bard uses to market and promote its products. Further, the documents were sent for simultaneous review.
Log 3	1766	11/16/2005	Uta Rosseck	Robert Carr; Michele Carter; Janet Hudnall; Judith Ludwig	Candi Long	Email reflecting legal advice of Suzanne Carpenter (Litigation Manager) about product samples provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Privilege cannot apply as Ms. Carpenter is now a lawyer and, therefore, cannot give legal advice. Further, Bard has not established how the communications reflects an issue of legal importance and/or did not have a sufficient business cause.
Log 3	1801	10/11/2005	Judith Ludwig	Shari Allen; Genevieve Balutowski; Brian Brown; Robert Carr; Kerry Chunko; Joe DeJohn; Wendy Hayes; Janet Hudnall; Brian Hudson; Jane Quackenbush; Gin Schulz; Cindi Walcott; David Zwald	John McDermott	Email reflecting legal advice of Suzanne Carpenter (Litigation Manager) about Recovery IVC Filter litigation and litigation hold provided to employees who need the information to perform their job functions and sent in anticipation of and furtherance of litigation.	Attorney-Client Privilege; Work Product	Privilege cannot apply as Suzanne Carpenter is not a lawyer and, therefore, she cannot provide legal advice. Bard has also failed to establish that these communications would not have been created in substantially similar form absent anticipated litigation.

Log 3	1879	2/10/2006	Shari Allen	Dennis Salzmann		Email and attachments reflecting legal advice of Judith Reinsdorf, Esquire about marketing strategies and regulatory compliance provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard alleges the communications are privileged as they relate to legal advice regarding an marketing strategies and regulatory complaince. However, the primary purpose of these communications was not to obtain or provide legal advice. These communications are a quality system audit regarding Bard's marketing policies and procedures. Such activities are general business obligations required of all medical device manufacturers. 21 C.F.R. 820.22. Thus, regardless of whether the audits and/or communications were created by a lawyer, the primary purpose for these communications was business related. Further, Plaintiff has repeatedly requested that Bard identify other quality audits not done by lawyers that satisfied Bard's regulatory obligations in a similar time frame. Bard has refused or is unable to do so. This suggests that Bard in attempt to manufacture privilege outsourced its normal business duties to a lawyer.
Log 3	1910	12/13/2006	Sue Hohmann	Kevin Shifrin; Linna Spurling	Shari Allen; Dennis Salzmann	Email regarding legal advice of Gina Dunsmuir, Esquire about sales meeting videos provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Plaintiff challenges bard's redaction of the final email in the chain. Bard's privilege claim should be denied as it has failed to establish that the communication was made for the primary purpose of soliciting legal advice or that confidentiality was expected or maintained. The communication did not include any lawyers and does not related to a matter of legal importance.
Log 3	1919	12/20/2007	Brett Enlow	Cindi Walcott		Email regarding legal advice about draft field message provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	This an email chain between none-legal employees regarding a letter to the sales force drafted by Brett Enlow and sent to non-lawyers for review and comment. Mr. Enlow states that "the field email will most likely being going out in the next day or so." Bard has redacted portions of the email chain and the entire message to the sales force. Bard's privilege claim should be denied as it has failed to establish that the communication was made for the primary purpose of soliciting legal advice or that confidentiality was expected or maintained. First, there is nothing that appears to be of legal significance in the communication. This is simply a marketing and sales communication, which is certainly not the type of traditional legal document discussed in the Vioxx case. Further, the body of the email suggests the document was final and was going out. This, there is no confidentiality.
Log 3	1965	12/6/2006	Brian Hudson	Stephanie Klocke; Natalie Wong		Email and attachments regarding legal advice of Brian Leddin, Esquire about G2 Jugular R002 provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard's claim of privilege should be denied as Bard has failed to establish that either the email or attachment was made for the primary purpose of requesting or providing legal advice. There is no question that Bard had an independent business duty under the FDA regulations (21 C.F.R. § 820.100) and its own procedures . (RA-STD-002 procedure, Ex. 2).Thus, there was a separate and sufficient cause for these communications to have taken place. Further, simply providing line edits on a non-traditional legal instrument is generally considered a general business matter.
Log 3	1973	1/17/2008	Genevieve Balutowski	Stephanie Klocke		Email and attachments regarding legal advice of Brian Leddin, Esquire about G2 Filter System corporate copy provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the primary purpose of the communication was to obtain or render legal advice or that confidentiality was maintained or expected. The in-house lawyer simply made line edits to a document that is not a tradional legal decoument. Further, this document is final and is meant to be shared broadly.

Log 3	2017	9/25/2006	Gin Schulz	Len DeCant; Heather Harmison; Brian Hudson; Stephanie Klocke; Ana Randall; Charlie Simpson; Gary Sorsher; Mark Walaska; Natalie Wong		Email regarding legal advice and request of Judith Reinsdorf, Esquire and Ed Basile, Esquire about audit report provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard alleges the communications are privileged as they legal advice regarding an "audit report" provided to employees who need the information to perform their job functions. However, the primary purpose of these communications was not to obtain or provide legal advice. These communications are a quality system audit regarding Bard's marketing policies and procedures. Such activities are general business obligations required of all medical device manufacturers. 21 C.F.R. 820.22. Thus, regardless of whether the audits and/or communications were created by a lawyer, the primary purpose for these communications was business related. Further, Plaintiff has repeatedly requested that Bard identify other quality audits not done by lawyers that satisfied Bard's regulatory obligations in a similar time frame. Bard has refused or is unable to do so. This suggests that Bard in attempt to manufacture privilege outsourced its normal business duties to a lawyer.
Log 3	2082	2/21/2008	Genevieve Balutowski	Stephanie Klocke; Inbal Lapid; Mike Randall	Ella Martin	Email and attachments reflecting legal advice of Dara Englert, Trademark Director, and Judy Murphy (Paralegal) and DeAnn Goodrich (Paralegal) about Label and IFU Approval provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the communication involves a request for legal advice from a lawyer. Instead, Bard is claiming that privilege should attach because a non-lawyer is independently giving legal advice. This arguemetn fails the most basic aspect of privilege.
Log 3	2097	4/14/2009	Brian Hudson	Gin Schulz; Robin Smithson		Email regarding request for legal advice of Richard North, Esquire about fracture report and provided to him in anticipation of litigation and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product	Bard has failed to establish that the primary purpose of these communication was to obtain or provide legal advice. Further, Bard has not established that these communications would not have been created in substnatially similar form but for anticipate dlitigation. This appears to be a month fracture summary report Bard created for its post-market surveillance of its filters. Bard intially claimed numerous such documents as privileged. However, Bard has since admitted such documents are not protected. However, in this case Bard seems to be claiming that privilege attached because it was forwarded to out-side counsel. This argument fails as the documents would have been created anyways and simply sending a document to a lawyer does not make it privileged.
Log 3	2099	4/6/2009	Brian Hudson	Bret Baird		Email requesting legal advice from counsel, Greg Dadika, Esquire and Gina Dunsmuir, Esquire, about sales force talking points and provided to other employees who need the information to perform their job functions.	Attorney-Client Privilege	This is an email chain with starting with an email on April 4, 2009 from Bret Baird to Bill Little, Brian Doherty, Greg Dadika, Gina Dunsmuit, Brian Hudson, and Gin Schulz. In the email, Mr. Hudson request simultaneous review and comments on a cover letter and talking points document he prepared for the sales force. Bard has now produced the email redacted but is still withholding the attachment. Bard has failed to establish that the primary purpose of this communication was to obtain legal advice. First, the subject matter is something that is far more closely relate to general business matter, i.e. instructing the sales force how best to promote the product to achieve sales. The fact that this was drafted by a non-lawyer and was submitted for simultaneous review further suggests the primary purpose of the communication as something other than to obtain legal advice. given that the attachment is not listed as in the email header, this entry presents another example of a poor technical production of ESI information.

Log 3	2177	7/2/2008	Brian Hudson	Cindi Walcott		Email reflecting legal advice of Suzanne Carpenter (Litigation Manager) and Greg Dadika, Esquire about response to patient provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	This is an email chain that was initiated when a patient implanted with a Bard Simon Nitinol Filter contacted NMT and then Bard raising concerns about long term viability, device malfunctions, and whether or not Bard recommended that he should be getting periodic imaging to evaluate the filter. There are a series of internal communications between Debra Griffith (Director, Medical Services & Support) and (Field Assurance Manager), and between them and Suzanne Carpenter (non-attorney from Bard's Legal department) regarding a response. Eventually Brian Hudson (quality engineer) is added to the email chain. Bard has now produced the email chain but redacted significant portions. Bard claims these portions reveal legal advice of Suzanne Carpenter. Bard has failed to establish privilege as there is no showing that any of these communications were made for the primary purpose of obtaining legal advice. None of the communications were made to or from a lawyer. Further, these communications were part of a general business duty, responding to patient request for safety information. Indeed, that is direct responsibility of Ms. Griffith's position.
Log 3	2244	10/7/2009	DeAnn Goodrich (Paralegal)	Jeffrey Pellicio	Bret Baird; Dara Englert (Trademark Manager)	Email containing legal advice of DeAnn Goodrich (Trademark Manager) regarding trademark registration.	Attorney-Client Privilege	Bard has failed to establish that the primary purpose of the communication was to obtain legal advice from a lawyer. The person alleged to be giving legal advice, is not a lawyers and, therefore, privilege cannot apply.
Log 3	2249	4/7/2009	Dara Englert (Trademark Manager)	Bret Baird	DeAnn Goodrich (Paralegal)	Email providing legal advice about G2 trademark protection.	Attorney-Client Privilege	Bard has failed to establish that the primary purpose of the communication was to obtain legal advice from a lawyer. Bard fails to identify any lawyer who was allegedly being asked to give and/or did give legal advice.
Log 3	2295	2/1/2010	Dara Englert (Trademark Manager)	Bret Baird	DeAnn Goodrich (Paralegal)	Email regarding legal advice about trademark issues.	Attorney-Client Privilege	Bard has failed to establish that the primary purpose of the communication was to obtain legal advice from a lawyer. The person alleged to be giving legal advice, is not a lawyers and, therefore, privilege cannot apply.
Log 3	2313	1/14/2010	Jeffrey Pellicio	Bret Baird		Email and attachments regarding legal advice of Gina Dunsmuir, Esquire about filter brochure provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard's claim of attorney-client privilege should be denied as Bard has failed to establish facts suggesting legal advice was being provided or solicited, or that confidentiality was maintained. The communication does not include legal personnel. Further, the email does not appear to involve a legal matter. Instead it appears to involve promotional material provided to customer. Such a document is not a traditionally legal instrument as discussed in the Vioxx case, and as such does not involve primarily legal advice. This appears similar to Joint Selection No. 36 from Phillips, where the court denied the privilege claim because while the in-house lawyer was being asked to review the attachments allegedly having to do with risk analysis, nothing in the email or the attachments themselves indicated that the document was a confidential communication either providing legal advice or soliciting legal advice
Log 3	2321	10/7/2010	DeAnn Goodrich (Paralegal)	Bret Baird; Jeffrey Pellicio	Dara Englert (Trademark Manager)	Email reflecting request for information for purposes of providing legal advice from Bard Corporate Legal Department regarding trademark and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the communication involves a request for legal advice from a lawyer. Bard has been unable to identify what lawyer was requested to or did in fact give legal advice.

Log 3	2377	2/24/2009	Mike Randall	Bret Baird		Email and attachments reflecting request for legal advice of Gina Dunsmuir, Esquire and Greg Dadika, Esquire about product risk review provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	This entry contains an email chain that has now been produced and an attachment that is still being withheld. The email chain begins with an email from Mike Randall dated February 5, 2009 to Brett Baird (Marketing Manager), Genevieve Balutowski (Regulatory Affairs Specialist), Jon Conaway (Quality Assurance), John Reviere (Director, Clinical Affairs), and Robert Carr with a subject line entitled "G2 Expand Completed Action item Summary." In the Body he requests review and comment on the draft so he can send it out "today". On the same day he responds to the same people that the summary has been updated based on their feedback. Jon Conaway then sends an email with the attached "G2 Expand Meeting Action Item Summary Final" to gin Schulz, Mike Randall and Robin Smithson requesting to speak ASAP. Bard claims the attachment reveals legal advice about a product risk review. Bard has failed to establish any facts suggesting the attachment was prepared for the primary purpose of soliciting legal advice. There are no lawyers involved in the email chain or listed as authors of the attachments. Further, the attachment seems to relate to a marketing and/or business plan relating the the G2 Filter. There does not appear to be anything indicating legal significance to the document. The emails also clearly indicates that the attachment was prepared by non-lawyers. [Appears to be same as Log 3, No. 3028].
Log 3	2401	9/3/2010	Joni Creal	Bret Baird; Jeffrey Pellicio		Email regarding legal advice of Gina Dunsmuir, Esquire about patient information packet provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the communication was made with the primary purpose of obtaining or providing legal advice. Notably, now lawyer is listed as part of the communication, nor as an author of the "patient packet." Further, there does not appear to be any legal significance to the communication. Rather, this appears to be a marketing communication.
Log 3	2445	6/4/2010	Debora Chavez	Suzanne Carpenter (Litigation Manager)	Cindi Walcott	Email regarding legal advice of Suzanne Carpenter (Paralegal) about incident investigation.	Attorney-Client Privilege; Work Product	First, this cannot be legal advice as Ms. Carpenter is not a lawyer. Second, Bard has failed to establish attorney-client privilege or work product as it has not established that this communication involved legal matters or that it would not have been created in substantially the same manner absent litigation. Ms. Walcott is tasked with investigating reported adverse events and ensuring adequate corrective actions are taken to prevent further failures as part of the FDA regulations and Bard's own procedures.
Log 3	2529	7/21/2009	Cindi Walcott	Bill Little	Gin Schulz	Email and attachments requesting legal advice of Suzanne Carpenter (Litigation Manager) about filter adverse event provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product	First, this cannot be legal advice as Ms. Carpenter is not a lawyer. Second, Bard has failed to establish attorney-client privilege or work product as it has not established that this communication involved legal matters or that it would not have been created in substantially the same manner absent litigation. These employees are tasked with investigating reported adverse events and ensuring adequate corrective actions to prevent further failures as part of Bard's mandatory requirements under FDA regulations and internal procedures.
Log 3	2617	8/6/2009	Bret Baird	David Ciavarella; Greg Dadika, Esquire; Gina Dunsmuir, Esquire; John Van Vleet	Bill Little	Email and attachments requesting legal advice about an Eblast script and potential legal implications of the same.	Attorney-Client Privilege	Bard has failed to establish that the attachment was prepared for the primary purpose of soliciting or providing legal advice from a lawyer. The attachments were not authored by a lawyer, they were sent for simultaneous review and comment, and communication related to business matter - a marketing eblast. To the extent the in-house lawyers commented on the materials they did so in a non-legal capacity. This is certainly not something traditionally considered a legal document.
Log 3	2625	5/20/2009	Bret Baird	DeAnn Goodrich (Paralegal)	DeAnna Porter	Email reflecting request for and legal advice about trademark renewal.	Attorney-Client Privilege	Bard has failed to establish that the communication involves a request for or rendering of legal advice from a lawyer. Instead, Bard is claiming that privilege should attach because a non-lawyer is independently giving legal advice.

Log 3	2626	5/20/2009	Bret Baird	DeAnna Porter		Email regarding legal advice of DeAnn Goodrich (Paralegal) about trademark renewal provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the communication involves a request for or rendering of legal advice from a lawyer. Instead, Bard is claiming that privilege should attach because a non-lawyer is independently giving legal advice.
Log 3	2828	10/22/2010	Bret Baird	BJ Reed	Jeffrey Pellicio	Email regarding legal advice of DeAnn Goodrich (Paralegal) about trademarks provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that the communication evidences a request for or rendering of legal advice from a lawyer. Contrary to Bard's claim, a non-lawyer cannot give independent legal advice.
Log 3	2846	4/6/2009	Bret Baird	Bill Little		Email regarding legal advice of Greg Dadika, Esquire about communication policy provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard has failed to establish that this entry reveals a confidential communication that was made primarily to obtain or render legal advice. There are no lawyers listed as being involved with the communication and Bard has not explained how a communication about a "communication policy" is a legal matter.
Log 3	3028	2/5/2009	Jon Conaway	Gin Schulz	Mike Randall; Robin Smithson	Email and attachments reflecting request for legal advice of Gina Dunsmuir, Esquire and Greg Dadika, Esquire about product risk review provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	<p>This entry contains an email chain that has now been produced and an attachment that is still being withheld. The email chain begins with an email from Mike Randall dated February 5, 2009 to Brett Baird (Marketing Manager), Genevieve Balutowski (Regulatory Affairs Specialist), Jon Conaway (Quality Assurance), John Reviere (Director, Clinical Affairs), and Robert Carr with a subject line entitled "G2 Expand Completed Action item Summary." In the Body he requests review and comment on the draft so he can send it out "today". On the same day he responds to the same people that the summary has been updated based on their feedback. Jon Conaway then sends an email with the attached "G2 Expand Meeting Action Item Summary Final" to gin Schulz, Mike Randall and Robin Smithson requesting to speak ASAP. Bard claims the attachment reveals legal advice about a product risk review.</p> <p>Bard has failed to establish any facts suggesting the attachment was prepared for the primary purpose of soliciting legal advice. There are no lawyers involved in the email chain or listed as authors of the attachments. Further, the attachment seems to relate to a marketing and/or business plan relating the the G2 Filter. There does not appear to be anything indicating legal significance to the document. The emails also clearly indicates that the attachment was prepared by non-lawyers.</p>
Log 3	3067	4/15/2009	Mike Randall	John Van Vleet	Bret Baird	Email and attachments regarding legal advice of Greg Dadika, Esquire about IVC filter Instructions For Use provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	The entry contains an email dated April 15, 2009 from Mike Randall to Brett Baird and John Van Vleet with an attachment entitled "FW:BPW G2 IFU Conference Call" and an attachment entitled "Memo on Filter IFU Revisions." There is also a prior email and attachment that Bard is withholding entirely. Bard claims these materials regard legal advice from Greg Dadika about IVC filter Instructions for use. Bard has failed to establish that any of these communications were confidential and made for the primary purpose of obtaining or providing legal advice. Bard has not established that the attachment was drafted by a lawyer or that it in anyway relates to something of legal significance. Further, there is no explanation for why employees from R&D would need a legal memorandum regarding Instructions for use.

Log 3	3077	2/11/2009	Mike Randall	Robert Carr; Abtihal Raji-Kubba		Email and attachments regarding legal advice of Greg Dadika, Esquire about IVC filter Instructions for Use provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	The entry contains an email dated February 11, 2009 from Mike Randall to Robert Carr and Abithal Raji-Kubba (Research and Development) with an attachment entitled "FW:BPW G2 IFU Conference Call" and an attachment entitled "Memo on Filter IFU Revisions." There is also a prior email and attachment that Bard is withholding entirely. Bard claims these materials regard legal advice from Greg Dadika about IVC filter Instructions for use. Bard has failed to establish that any of these communications were confidential and made for the primary purpose of obtaining or providing legal advice. Bard has not established that the attachment was drafted by a lawyer or that it in anyway relates to something of legal significance. Further, there is no explanation for why employees from R&D would need a legal memorandum regarding Instructions for use.
Log 3	3089	2/6/2009	Mike Randall	Bret Baird; Genevieve Balutowski; Robert Carr; Patty Christian; Jon Conaway; Gina Dunsmuir, Esquire; Bill Little; Mike Randall; John Reviere; Richard North, Esquire; Dennis Salzmann; Gin Schulz; John Van Vleet	Greg Dadika, Esquire; Abtihal Raji-Kubba	Email and attachments reflecting request for legal advice of Gina Dunsmuir, Esquire and Greg Dadika, Esquire about product risk review provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product	Bard describes this as an email and attachment sent by Mike Randall on February 6, 2009 to 12 non-lawyers, three in-house counsel, and Richard North reflecting legal advice of Gina Dunsmuir and Greg Dadika about a product risk review. This appears to be a similar documents to what the <i>Phillips</i> court determined to not be privileged in Joint Selection No. 36. Bard has failed to establish that these were confidential communications made for the primary purpose of obtaining or providing legal advice. Notably, Bard has refused to identify who authored the attachments. Further, numerous other alleged "risk reviews" have turned out to be monthly summaries of failures that were being collected and submitted to Bard management to comply with regulatory requirement of engaging in post-market surveillance. Further, the breadth and simultaneous nature of the disclosure suggests that it was not confidential and was not for the primarily legal purpose. Bard has also failed to establish that the communication would not have been made in a substantially similar form but for anticipated litigation.
Log 3	3161	3/23/2010	Mike Randall	Nikki Church (Legal Assistant)	Gina Dunsmuir, Esquire; Adam Rappaport, Esquire	Email and attachments reflecting legal advice of attorneys Adam Rappaport and Gina Dunsmuir regarding filter study sent to employees who need the information to perform their job functions.	Attorney-Client Privilege	This entry is long email chain regarding a request by physicians at the University of Michigan to have Bard fund a study on IVC filters that they were proposing. The final email in the chain is an email from Mike Randall (Project Lead, Research & Development) to Nikki Church (Document Control) and copied to two in-house lawyers. Mr. Randall mentions that attached to his email is "signed off grant request," the study proposal, and the University Policy on grants. Documents are sent to "Document Control" when they are finalized, so that all final documents can be preserved. Mr. Randall confirms this by asking Mr. Church to let him know if she need any further information. There is nothing about his email that suggest these attachments were being transmitted to obtain legal advice from a lawyer. Rather, these business attachments are being sent so that the proposed study can be funded by Bard.
Log 3	3184	9/29/2009	Cindi Walcott	Brian Hudson		Email with legal advice of Suzanne Carpenter (Litigation Manager) about litigation file created in anticipation of and furtherance of litigation and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product	Bard describes the entry as an email dated September 29, 2009 from Cindi Walcott (Field Assurance Manager) to Brian Hudson (Quality Engineering Manager) regarding legal advice of Suzanne Carpenter (non-lawyer) about a litigation file. First, this cannot be legal advice as Ms. Carpenter is not a lawyer. Second, Bard has failed to establish attorney-client privilege or work product as it has not established that this communication involved legal matters or that it would not have been created in substantially the same manner absent litigation. These employees are tasked with investigating reported adverse events and ensuring adequate corrective actions to prevent further failures as part of Bard's mandatory requirements under FDA regulations. There is nothing to suggest that they are doing anything different here, regardless of whether the adverse event was reported as part of a lawsuit or directly from a doctor.

Log 3	3271	3/5/2009	Cindi Walcott	Anisa Kosta; Jesse Portillo	Natalie Wong	Email regarding legal advice of Suzanne Carpenter (Litigation Manager) about legal file provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product	Bard describes the entry as an email dated March 5, 2009 from Cindi Walcott (Field Assurance Manager) to Anisa Kosta (Field Assurance Engineer) and Jesse Portillo and copied to Natalie Wong (Quality Assurance Engineer) regarding "legal advice of Suzanne Carpenter [non-attorney] about a legal file...." Bard has failed to establish attorney client privilege or work product as it has not established that this communication involved legal matters or that it would not have been created in substantially the same manner absent litigation. No lawyer is listed as being associated with this alleged legal advice and all of these employees are tasked with investigating and creating complaint files for reported adverse events as part of Bard's mandatory reporting requirements under FDA regulations.
Log 3	3465	8/9/2010	Robert Carr	Adrian Ravenscroft	Richard North, Esquire	Email sent in anticipation of and in furtherance of potential and ongoing product liability litigation matters regarding deposition preparation.	Attorney-Client Privilege; Work Product	Adrian Ravenscroft worked for Nitinol Medical Technologies, Inc. and helped design the Recovery Filter. He was deposed in a Bard Filter case in late October 2010. This email is dated a little over two months before that deposition and is from Robert Carr to Mr. Ravenscroft and copied to outside counsel. Plaintiff has repeatedly requested that Bard identify if and when Mr. Ravenscroft retained Mr. North. Bard has refused to provide an answer. Therefore, Bard has failed to establish that an attorney-client relationship existed between Mr. North and Mr. Ravenscroft. Further, there is no explanation for why Mr. Carr was the person communicating with Mr. Ravenscroft. To the extent that the communication represents Bard soliciting a witness to have Mr. North represent him and/or suggesting how he should respond to factual inquiries, no privilege applies. Further, Bard has failed to establish how work product was not waived by disclosure to a third party.
Log 3	3746	12/6/2006	Pete Palermo	Brian Hudson	Gin Schulz	Email and attachments reflecting legal advice, comments, and edits of Brian Leddin, Esquire about product action plan provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	Bard's privilege claims should be denied as Bard has failed to establish that the primary purpose of the communication was to obtain or provide legal advice. No lawyers as listed as being a party to the communication. Further, it is undeniable that Bard was required by both FDA regulations (21 C.F.R. § 820.100) and its own procedures to create the Remedial Action Plan to promote patient safety. Thus, there is a sufficient reason for these communications to have taken place. Further, this is not a traditional legal instrument as described in the Vioxx case, which would be subject to privilege. Bard should not be allowed to obtain privilege through the mechanism of inserting lawyers into its required business duties.
Log 3	3757	1/31/2006	Suzanne Carpenter (Litigation Manager)	Cindi Walcott	Gin Schulz	Email reflecting request for and legal advice about filter samples and ensuring compliance with FDA regulations.	Attorney-Client Privilege	The privilege claim should be denied as Bard has not established any facts evidencing that this communication was made for the primary purpose of obtaining or providing legal advice. No lawyers are a party to the communication and even claimed to be associated with it. Moreover, the description expressly stated that communication was being made to comply with FDA regulations – which is a business reason.

Log 3	3804	10/13/2006	John McDermott	Gin Schulz		Email reflecting legal advice of Judith Reinsdorf, Esquire about communicatio to sales force and potential legal implications of the same and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	<p>Entries from Log 3, Nos. 175, 505.01, 519, 520.01, 521, 523 and 3804 all invovle the same disputed information. This is an email chain that begins with John McDermott emailing Judith Reinsdorf (Vice President, Secretary, and General Counsel of C.R. Bard) on October 10, 2006 and copying Brian Barry, Dr. Ciavarella, Christopher Ganser, Shari Allen, Janet Hudnall, and Gin Schulz with the subject line "G2", as in G2 Filter. The email apparently contained an attached "action and communication" plan prepared by Mr. McDermott. Ms. Reinsdorf replies on October 12, to Mr. McDermott and copies John Weiland, and Brian Barry. She notes that she has reviewed Mr. McDermott's action and communication plan with Brian Barry and John Weiland and they are in agreement on a number of issues regarding the plan, which she goes on to identify. The entire email is the forwarded four more times and is seen by multiple different employees, including for example Cindi Walcott (Field Assurance Manager), who is responsible for investigating adverse events.</p> <p>Bard's privilege claim should be denied as it has failed to establish that the communication was made for the primary purpose of soliciting legal advice or that confidentiality was expected or maintained. First, there is nothing that appears to be of legal significance to the communications. This is simply a marketing communication, which is certainly not the type of traditional legal document discussed in the Vioxx case. Further, while Ms. Reinsdorf is a lawyer, she also held the positions of Vice President and Secretary for C.R. Bard. Thus, she was not necessarily acting in her role as a lawyer. The initial email was also sent out for simultaneous review and comment to other non-lawyers. Indeed, Ms. Reinsdorf makes it clear that she did in fact review the plan with other non-lawyers and that her suggestions were reached jointly with the non-lawyers. This strongly indicated that the primary purpose was business related. Finally, Bard has not established why the numerous employees who were provided with this email chain needed it to fulfill the purpose for why the lawyer was consulted.</p>
Log 3	3912	5/15/2009	John Van Vleet	Brian Doherty; Bill Little; Mike Warren	Gin Schulz; Sue Stonecipher	Document reflecting information and legal advice of Gina Dunsmuir, Esquire and Greg Dadika, Esquire, about filter investigation provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	<p>The document is alleged to be an email dated May 15, 2009 from a regulatory and clinical affairs manager to a Sales Manager (Mr. Doherty), a Human Resources Manager (Mr. Warren), a Marketing Manager (Mr. Little), and copied to VP of Regulatory Assurance (Ms. Schulz) and an Administrative Assistant (Ms. Stonecipher), which reflects legal advice of in-house lawyers about a filter investigation. Bard has failed to establish that how this communication reveals a confidential communication that was made primarily to obtain or render legal advice. There are no lawyers listed as being involved with the communication, and Bard has not explained why this alleged filter investigation is not just part of Bard's normal failure and design investigations. Further Bard has not established why this broad swath of different departments needed to have the information to fulfill the function for which the lawyer was consulted.</p>
Log 3	3987	8/10/2010	John Van Vleet	Jim Beasley; Brian Doherty; Bill Little; Abtihal Raji-Kubba; Gin Schulz	Gina Dunsmuir, Esquire	Email requesting legal advice about IVC filter article and provided to employees who need the information to perform functions.	Attorney-Client Privilege	<p>Bard's claim of attorney-client privilege should be denied as Bard has failed to establish that the communication reveals a confidential solicitation for or rendering of legal advice from a lawyer. Here, a regulatory and clinical affairs manager emails a sales manager, a marketing manager, a research and development manager, VP of quality assurance, and the President of Bard Peripheral Vascular and copies in-house counsel and allegedly requests legal advice regarding an IVC filter article. Bard has not provided any facts explaining how how or why legal advice was implicated regarding a medical article. Further, given that counsel was merely copied is suggestive that this was really a business communication. Finally, Bard has not explained why such a wide range of personnel would need the alleged legal advice to fulfill the purpose for which the advice was sought.</p>

Log 3	4025	5/22/2006	Luke Harada	Brian Barry; Ela Bochenek, Esquire; Mark Carow; Joe Cherry; David Ciavarella; John DeFord; David Dimmit; Robert Entwistle; Christopher Ganser; Thomas Klein, Esquire; Charles Krauss, Esquire; Stephen Long, Esquire; Scott Lowry; Jack Myers, Esquire; J.R. O'Farrell, Esquire; Judith Reinsdorf, Esquire; Eric Shick; George Thayer; John Warburton	Jim Brann; Robert Carr; Ben Davis; Francis Deleplanque; Scott Jones; Sajini Joshi; Michael Lee; Bob Mellen; Carl Rickenbaugh; Steve Smith; Larry White	Portion of document reflecting legal advice of outside counsel and in-house counsel regarding acquisition.	Attorney-Client Privilege	BPVEFILTE R-01-00213619	BPVEFILTE R-01-00213619	Bard's claim of attorney-client privilege should be denied as Bard has failed to establish that communication reveals a request to or rendering of advice from a lawyer, disclose any facts suggesting legal advice was being provided or solicited, or that confidentiality was maintained. Bard provides no explanation for why all of the identified persons needed the information to fulfill the legal purpose which a lawyer was allegedly consulted.
Log 4	4	3/15/2004	Donna Passero, Esquire	Mary Edwards, John Lehmann, Christopher Ganser, Paul Kowalczyk, Brian Berry	Janet Hudnall, Doug Uelmen, Joe DeJohn, Len DeCant, John McDermott	Email requesting and reflecting legal advice of Donna Passero, Esquire regarding sales force communications provided to employees who need the information to perform their job functions	Attorney-client privilege			Bard describes this as a single email dated March 15, 2004 from Donna Passero to Mary Edwards, John Lehmann, Christopher Ganser, Paul Kowalczyk, Brian Barry and copied to Janet Hudnall, Doug Uelmen, Joe DeJohn, Len DeCant, John McDermott and "reflecting Ms. Passero's legal advice regarding sales force communications. This appears to be the same email chain that was challenge in the Phillips case as Joint Selection 5. The court found that "the 'primary purpose' of the communication is a business determination with no apparent legal implication." Phillips v. C.R. Bard, Inc., 290 F.R.D. 615, 645 (D. Nev. 2013). Whether or not this is the same email chain, Bard has failed to establish that the primary purpose of the communication was to obtain or solicit legal advice. There is no legal significance to informing the sales force of a device failure. At most, this is simply editing a traditionally non-legal document.
Log 4	28	2/17/2004	Chris Ganser	Dr. John Lehmann		Email reflecting communication to outside legal counsel, Howard Holstein, Esquire, for purposes of obtaining legal advice concerning patient complication and provided to employees who need the information to perform their job functions.	Attorney-client privilege			This is an email dated February 17, 2004 from Christopher Ganser to regulatory consultant and lawyer Howard Holstein and copied to Brian Barry and Tim Ring. The email mentions a long standing relationship and that Mr. Holstein is going to help Bard review an issue. The rest of the email describes factual information related to the first patient death from a Recovery filter migration. Nothing in the email describes legal advice being solicited or rendered. Indeed, it unclear from the email if Mr. Holstein is actually being asked to consult as a lawyer. <i>See, In re Viox Prods. Liab. Litig., 501 F. Supp. 2d 789, 798</i> (E.D. La. 2007)("[o]nly if the attorney is 'acting as a lawyer' -- giving advice with respect to the legal implications of a proposed course of conduct -- may the privilege be properly invoked."). In fact, Mr. Holstein is withing days listed as a "team member" on the design investigation team that is opened in response to this failure. Mr. Ganser then forwards the email to Dr. Lehmann with an attached MAUDE data summary. Bard's privilege claim should be denied as Bard has failed to establish that this communication reveals a request for or rendering of legal advice. This email simply reveals facts and that Mr. Holstein is being asked to assist on a product investigation, that Bard was required to do under its regulatory obligations.
Log 4	29	5/10/2001	Elizabeth Dunn (Bard Law Department)	Suzanne Carpenter (Paralegal)		Fax regarding product failure analysis to Suzanne Carpenter (Litigation Manager) sent in furtherance of providing information to the legal department needed for providing legal advice.	Attorney-client privilege			This is described as a fax transmission dated May 10, 2001 from Elizabeth Dunn (non-lawyer) to Suzanne Carpenter (non-lawyer) regarding a "product failure analysis." Bard's claim of attorney-client privilege should be denied as Bard has failed to establish that the communication reveals a request for or rendering of advice from a lawyer, and because Bard failed disclose any facts suggesting legal advice was being provided or solicited. Notably, the communication does not involve a lawyer and Bard has refused to identify any specific lawyer that was associated with this communication.

Log 5	41	6/13/2007	Lori Collins	Mori Ament	Sandy Kerns	Email concerning litigation and potential adverse events provided to employees who need the information to perform their job functions.	Attorney-Client Privilege; Work Product	BPV-COMP-00016012	BPV-COMP-00016124	This is an email that was authored by Lori Collins (Field Assurance Manager) on June 13, 2007 and sent to Mori Ament (Field Assurance Administrator) and copied to Sandy Kerns (Field Assurance Coordinator). Bard describes the material as concerning litigation and potential adverse events. First, attorney-client privilege cannot apply as Bard has failed to describe any facts suggesting that the communication evidences a request for or rendering of legal advice from a lawyer. Second, neither privilege or work product attaches as Bard has not established that this communication would not have been created in substantially similar form regardless of any litigation concerns. All of the employees involved with this communication are from the Field Assurance group. This group is assigned the responsibility of investigating and creating complaint files for report adverse events. This is a general business requirement for all device manufacturers. Furthermore, the document is kept within the general complaint file, so it was not segregated from non-protected materials and may be viewed by all Bard personnel.
Log 5	92	5/30/2007	Dennis Salzmann	Gina Dunsmuir, Esquire	Michele Carter; Joe DeJohn; Sue Hohmann; Mark Kunning; Lindsay Pack; Uta Rosseck; Mike Ryan; Kevin Shifrin; Mark Wilson	Email and attachments regarding legal advice about marketing policy.	Attorney-Client Privilege			This is an email dated May 30, 2007 by Dennis Salzmann forwarding attachments to Gina Dunsmuir (in-house counsel) and copying Michele Carter (Marketing Manager), Joe DeJohn (VP, Sales) Sue Hohmann (Manager, Marketing Communications) Mark Kunning (Director, Prof. Development), Lindsay Pack (Regulatory Affairs Associate), Uta Rosseck (Marketing Manager), Mike Ryan (Regulatory Affairs Program Manager), Kevin Shifrin (VP, Marketing) and Mark Wilson (Quality Engineer). Bard alleges the communications are privileged as they provide "legal advice about marketing policy." However, Bard has failed to establish that the primary purpose of the communication was to obtain or provide legal advice. Notably, despite repeated requests, Bard has refused to identify the author of the attachments. Additionally, Plaintiff suspects that this communication is actually the result of a quality system audit regarding Bard's marketing policies and procedures. Such activities are general business obligations required of all medical device manufacturers. 21 C.F.R. § 820.22. Thus, regardless of whether the audits and/or communications were created by lawyer, the primary purpose for these communications were business related. Further, given the wide distribution to marketing, sales, engineering, and professional development, Bard has not shown that confidentiality was expected or maintained.
Log 5	194	5/14/2004	David Ciavarella	Janet Hudnall	Brian Barry; Mary Edwards; John Lehmann	Email reflecting a request for legal advice from Donna Passero, Esquire about hospital filter presentation and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	BPVEFILTE R-01-00043574	BPVEFILTE R-01-00043575	Bard's claim of attorney-client privilege should be denied as Bard has failed to: establish that the communication reveals a solicitation for or rendering of advice from a lawyer, disclose any facts suggesting legal advice was being provided or solicited, or that confidentiality was expected or maintained. The communication only involves non-legal personnel and appears to relate to a non-legal matter, marketing ("hospital filter presentation"). This likely involved a presentation made to a hospital following a patient death, in which Bard personnel tried to convince the hospital to continue to use the product.

Log 5	202	4/25/2004	John Lehmann	Donna Passero, Esquire	Christopher Ganser	Email and attachments providing information to legal counsel for purposes of obtaining legal advice for company about draft Health Hazard Evaluation.	Attorney-Client Privilege	<p>This is an email and attachment dated April 25, 2004 from John Lehmann to Donna Passero and copying Christopher Ganser. The express subject matter of these communications is Dr. Lehmann providing information to assist with the preparation of a Health Hazard Evaluation. There is no question that Bard and Dr. Lehmann specifically had separate and sufficient business obligations to gather information and to help prepare the Health Hazard Evaluation. This is required by 21 C.F.R. 820.100 and Bard's own specific policy and procedure regarding product failures and corrective action investigations. See, Ex. 2, at p. BPVE-17-01-00024669 ("The Corporate Medical Director is required to help consult with the divisional team in creating the remedial action plan and in a creating a health hazard evaluation, which must be included with the remedial action plan.")</p> <p>The question becomes, therefore, can Bard use its in-house counsel as a middleman to redistribute normally required business activities so as to obtain privilege. The answer should be no. See, <i>United States v. Chevron Texaco Corp.</i>, 241 F. Supp. 2d 1065, 1076 (N.D. Cal. 2001)("[n]o privilege can attach to any communication as to which a business purpose would have served as a sufficient cause, i.e., any communication that would have been made because of a business purpose, even if there had been no perceived additional interest in securing legal advice."). Bard has not provided any facts suggesting that there was not a sufficient business purpose for these communications to have been created.</p>
Log 5	203	4/19/2004	Brian Barry	John Lehmann		Email reflecting information provided to Donna Passero, Esquire for purposes of obtaining legal advice about product complaint and provided to employees who need the information to perform their job functions.	Attorney-Client Privilege	<p>This is an email dated April 19, 2004 from Brian Barry to John Lehmann, in which Mr. Barry thanks Dr. Lehmann for his "Review of Miami Recovery patent autopsy report." There is a prior email that is redacted, which likely contained factual information about the deceased patient. Bard claims attorney-client privilege because the review was allegedly commissioned by Donna Passero. Bard's claim should be denied as Bard cannot show that the primary purpose of Dr. Lehmann's review was to obtain legal advice. Bard is required under 21 C.F.R. 820.100 to investigate adverse events, to determine if corrective action is needed, and to ensure such action is sufficient to prevent future failures. Indeed, Bard's prior Remedial Action Plans and Health Hazard evaluations included an analysis by Dr. Lehmann of the autopsy. Thus, there was clearly a sufficient business reason for this review to have occurred. The question becomes, therefore, can Bard use its in-house counsel as a middleman to redistribute normally required business activities so as to obtain privilege. The answer should be no. See, <i>United States v. Chevron Texaco Corp.</i>, 241 F. Supp. 2d 1065, 1076 (N.D. Cal. 2001),"[n]o privilege can attach to any communication as to which a business purpose would have served as a <i>sufficient cause</i>, i.e., any communication that would have been made because of a business purpose, even if there had been no perceived additional interest in securing legal advice."</p>
Log 5	257	6/15/2004	John Lehmann	Christopher Ganser		Email and attachments concerning work performed for Bard Law Department for purposes of providing legal advice and for product liability litigation.	Attorney-Client Privilege; Work Product	<p>Bard claims this entry is an email from Dr. Lehmann to Christopher Ganser with an attachment listed his hours worked for Bard's Law Department on litigation matters. In the recent motion regarding the Lehmann Report, Bard claimed Dr. Lehmann stopped performing any consulting work for Bard by May 2004. Plaintiff believes that the attachment will demonstrate that Dr. Lehmann was in fact still performing the same general consulting services for Bard in May 2004. To the extent that Dr. Lehmann's bill reflects work on Remedial Action Plans (often called RAPS), Health Hazard Evaluations, or conversations with members of the Product Assessment Team, such as Messers. Carr or Uelmen, those portions should not be redacted. To extent this is the case, such work was performed as part of Bard's normal business obligations to investigate product defects and potential corrective actions (21 C.F.R. 820.100). Simply sending the bill to an attorney does mean that privilege or work product attaches.</p>

Log 6	8	2/20/2012	N/A	N/A		Portion of document seeking legal advice of Sabina Downing (Litigation Manager), and Suzanne Carpenter (Litigation Manager), about Filter litigation.	Attorney-Client Privilege; Work Product	BPVEFILTE R-01- 00100020	BPVEFILTE R-01- 00100020	This is a document dated February 20, 2012 with no listed author or recipient. Bard claims privilege and work product protection on the basis that it reflect "legal advice" that was sought from two non-lawyer employees, Sabina Downing and Suzanne Carpenter, about filter litigation. Bard refers to these employees as "Litigation managers." Bard has failed to establish privilege as no facts have been presented supporting that the communication reveals a solicitation for or a rendering of legal from a lawyer. Bard has also failed to establish work product protection as no facts were presented to indicate that this communication was not made because of normal business activities, i.e. investigation and creation of complaint files as required by the FDA. Finally, Bard has not acted to preserve confidentiality given that the allegedly protected material is kept in the general complaint database that anyone at Bard can access.
Log 6	54	9/23/2010	Patty Christian	John DeFord	Gina Dunsmuir, Esquire	Email reflecting legal advice of Gina Dunsmuir, Esquire about the response to a request for information provided to employees who need the information to perform their job function.	Attorney-Client Privilege			This an email chain with an attachment, with the first email being sent by Gina Dunsmuir (in-house counsel) on September 23, 2010 to John Deford (Senior Vice President, Science, Technology, and Clinical Affairs) and Patty Christian (Vice President Regulatory Affairs). The email has an attachment, which consists of Ms. Dunsmuir editing a letter prepared by someone with the initials JVV. The letter is a response to a communication from the Agency for Health Care Research and Quality apparently requesting that Bard identify published studies it was aware of regarding clinical outcomes for its filters. [Again Bard's ESI vendor appears to have had technical difficulties as no attachment line is listed.] Ms. Christian responds on the same day that she accepted the edits. Bard's claim of privilege should be denied as Bard has failed to establish that either the email or attachment was made for the primary purpose of requesting or providing legal advice. As discussed in the <i>Vioxx</i> case, simply providing line edits or commenting on traditional business matters such as scientific reports, articles, study proposals, or marketing matters is not providing primarily legal advice. <i>In re Vioxx Prods. Liab. Litig.</i> , 501 F. Supp. 2d 789, 801-03 (E.D. La. 2007). Further, this communication is not analogous to Warning Letter from the FDA, where formal findings of safety violations have been made. Bard is simply responding to a request to identify what medical literature may exist regarding its products. Finally, confidentiality cannot exist over the attachment as the email indicated it was approved and was being distributed to a third party.
Log 6	65	1/20/2010	John Van Vleet	John DeFord		Email and attachments reflecting legal advice of Gina Dunsmuir, Esquire about promotional practices provided to employees who need the information to perform their job function.	Attorney-Client Privilege			Bard's claim of attorney-client privilege should be denied as Bard has failed to: establish that the communication reveals a solicitation for or rendering of advice from a lawyer, disclose any facts suggesting legal advice was being provided or solicited, or that confidentiality was maintained. The communication does not include legal personnel. Instead it is a communication between two regulatory and clinical affairs employees John Van Vleet and John Deford. Further, the email does not appear to involve a legal matter. Instead it appears to involve a traditional business matter, promotional and marketing practices. <i>See, Phillips v. C.R. Bard, Inc.</i> , 290, F.R.D. 615, 644, 653-654 (D. Nev. 2013)(finding Joint Selection No. 5 (Sales Communication) and No. 29 (Colleague letter) not privileged). Bard has also failed to identify who authored the attachments. Finally, to the extent the attachments represent a discussion of a quality audit, such activity was required by a business requirement under 21 C.F.R. 820.22.

Log 6	107	6/26/2012	John DeFord	Todd Garner; Chris Holland; Tim Ring; John Weiland	Sharon Alterio; Jim Beasley; Tim Collins	Email and attachments reflecting legal advice of Greg Dadika, Esquire and outside counsel about a medical article provided to employees who need the information to perform their job function.	Attorney-Client Privilege	This is an email chain that starts with an email dated June 25, 2012 from Joseph Thorton (lawyer for a publishing entity) to Jane Davis (outside counsel for Bard) apparently regarding a request Ms. Davis made for a correction regarding an article. She then forwards the email to some redacted source on the same day. Somehow the email gets to Greg Dadika (in-house counsel) who then forwards it to John DeFord (Senior Vice President, Science, Technology, and Clinical Affairs), Jim Beasley (President, BPV), John Van Vleet (Senior Manager, RA/CA) and Brian Leddin (in-house counsel). John Deford then forwards the email chain to Tim Ring, John Weiland, Chris Holland, and Todd Garner, and copies Jim Beasley, Sharon Alterio, and Tim Collins. Three of these recipients are not listed on the list of Bard's employees it provided (employees (Chris Holland, Todd Garner, Sharon Alterio), but they have Bard email addresses so Plaintiffs will presume them to have been Bard employees. Privilege should not apply to these communications because these communications do not evidence a rendering of or solicitation for legal advice. The only discussion taking place seems to be of a published medical study and the conclusions reached therein. Further, given the wide distribution list, confidentiality was not expected or maintained.
Log 6	109	9/17/2010	Gin Schulz	Jim Beasley	Abtihal Raji-Kubba	Email and attachments reflecting legal advice of Brandee Kowalzyk, Esquire, Gina Dunsmuir, Esquire, and Brian Leddin, Esquire about physician communications provided to employees who need the information to perform their job	Attorney-Client Privilege	This is an email dated September 17, 2010 with attachments sent from Gin Schulz (Quality Assurance) to (President, BPV) and copied to Abtihal Raji-Kubba (Senior Manager, R&D) and allegedly reflects the legal advice of two in-house and one external lawyer about "physician communications." Privilege does not apply as Bard has failed to establish that the communication reveals a request for or rendering of advice from a lawyer, discloses any facts suggesting legal advice was being provided or solicited, or that confidentiality was expected or maintained. According to the log entry, the communication does not include any lawyers. Further, Bard does not provide any factual support for claim that the communication provides or solicits legal advice. Even if legal advice was being sought, Bard has not explained why an R&D employee needed to be made aware of legal advice regarding a communication to physicians. Further, Bard has failed to identify who authored the attached communications.
Log 6	115	10/21/2009	Tim Ring	Diana Doyle		Email and attachments reflecting legal advice of Stephen Long, Esquire about communications about product litigation provided to employees who need the information to perform their job function.	Attorney-Client Privilege	This is an email with an attachment dated October 20, 2009 sent by Stephen Long (in-house counsel) to Tim Ring (Chairman & Chief Executive Officer), John Weiland (President, COO), Todd Schermerhorn (Senior Vice President and Chief Financial Officer), John Deford (Senior Vice President, Scient, Technology, and Clinical Affairs) and Eric Shick (Vice President, Investor Relations). The subject of the email is an upcoming presentation to shareholders and the attachment is the talking points for all of those involved. Of note, Bard has been unable to identify who wrote the attachment and has refused Plaintiffs request to examine the metadata as to the author. Privilege does not apply as Bard has failed to establish that the communication reveals a request for or rendering of advice from a lawyer, disclose any facts suggesting legal advice was being provided or solicited, or that confidentiality was expected or maintained. First, the subject matter here does not appear legal in nature. This about a script that is being used during a meeting with shareholders. This is certainly not something that is traditionally legal in nature as discussed in the <i>Vioxx</i> decision. Second, confidentiality was not maintained as the talking points were disclosed to shareholders. Third, Bard has not even established that the in-house lawyer authored the attachment.
Log 6	121	10/21/2009	Tim Ring	Diana Doyle		Email and attachments reflecting legal advice of Stephen Long, Esquire about communications about product litigation provided to employees who need the information to perform their job function.	Attorney-Client Privilege	Duplicate of Log 6, 115.

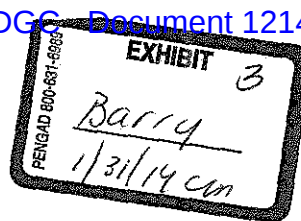
Log 6	128	2/7/2008	Gosen, Janie	Tim Ring	Mark Carow; Janel Fillinger; Chris Hartz; Brian Kelly; Amy Paul; Barbara Scrivens; Dan Silver; Barbara Vincelli; John Weiland	Portion of document reflecting legal advice of Bard Legal Department about contract wording provided to employees who need the information to perform their job function.	Attorney-Client Privilege	BPVEFILTE R-01- 00199342	BPVEFILTE R-01- 00199346	The entry is described as an email dated February 2, 2008 from Janie Gosen (non-lawyer) to Tim Ring and numerous other nonlawyers, many of whom are not listed on the list of Bard employees provided by Bard. Bard claims privilege as the document "reflects legal advice of Bard Legal Department about contract wording...." Plaintiff conceded that if Bard establishes that the communication reveals legal advice from Bard's in-house lawyer about contract provisions it would be privileged. That being said, Bard has not established that the communication even reveal a solicitation of advice from an attorney, that the communication in facts provided or solicited legal advice, or that confidentiality was maintained or expected. Of note Bard fails to identify what lawyer is allegedly providing legal advice and there is broad distribution to numerous people, some who do not appear to have been lawyers, with no discussion of why they needed the information to fulfill the purpose for why a lawyer was allegedly consulted.
Log 6	130	4/21/2006	Dastgheib, Barbara	Joe Cherry; Robert Entwistle; Christopher Ganser; Todd Garner; Charles Grom; Stephen Long, Esquire; Scott Lowry; Michael Monteleone; Kevin Mulkerin; Jim Natale; Judith Reinsdorf, Esquire; Tim Ring; Todd Schermerhorn; Eric Shick; John Weiland	Patty Camfield; Claribel Crudup; Diana Doyle; Janice Dudzak; Christine Siburn; Sandy Stannard	Email and attachments reflecting legal advice of various attorneys about disclosure controls and procedures and provided to employees who need the information to perform their job function.	Attorney-Client Privilege			This is an email chain starting with email from Stephen Long (in-house counsel) to Barbara Dastgheib on April 20, 2006 with attachments.[Of note, defendants production of ESI appears to have suffered technical problems as no attachment line is noted.] Ms. Dastgheib (Traveller Scheduler) then forwards the email and attachments to over 20 recipients, all of whom are non-lawyers except two in-house lawyers. The Subject title is FW: Disclosure II and the body of the email describes the attachment as materials for the Committee meeting. Bard claims the materials are privileged because the reflect legal advice of undisclosed attorneys regarding "disclosure controls and procedures." Bard has failed to establish that the primary purpose of these communications were to solicit or provide legal advice from an attorney or that confidentiality was expected or maintained. Bard has not established what attorneys provided legal advice, or how this advice was allegedly legal in nature. Instead, this document appears to relate to general business obligations required by any corporation and is not a traditional elgal document. Moreover, the information was clearly meant for wide disclosure.
Log 6	167	8/6/2010	Tim Ring	Todd Schermerhorn	John Weiland	Email seeking legal advice of Stephen Long, Esquire and Brian Leddin, Esquire about a media request provided to employees who need the information to perform their job function.	Attorney-Client Privilege			Although not revealed in the privilege log, this entry contains multiple emails in a chain. The email evidences a discussion amongst Bard officers of a request by a media person for comment on medical article that was about to be released to the public. While in-house counsel are copied on some of the emails, neither Bard or the document itself evidence that in-house counsel was being asked to provide legal advice or that the communications were meant to be confidential. Further, mitigating against that conclusion is the fact that in-house counsel as just copied on the communications.
Log 6	191	2/21/2013	Mike Connors	Alex Tessmer		Email reflecting legal advice of the Bard Legal Department about filter litigation preparation and discovery provided to employees who need the information to perform their job function.	Attorney-Client Privilege; Work Product			The entry is described as an email between between Mike Connors (programmer) and Alex Tessmer (engineer) allegedly "reflecting legal advice" of "Bard's Legal Department." Bard's claim of attorney-client privilege should be denied as Bard has failed to establish that communication reveals a request to or rendering of advice from a lawyer, disclose any facts suggesting legal advice was being provided or solicited, or that confidentiality was maintained. Notably, the communication does not involve any lawyer and Bard fails to identify any specific lawyer that was solicited to provide and/or did provide legal advice. Bard's mentions the law department, but as seen elsewhere Bard believes non-lawyers may give their own independent legal advice. Bard has also failed to provide sufficient facts establishing that the communication was prepared because of anticipated litigation.

Log 6	193	10/11/2005	Kellee Jones	Rich Bliss	Email reflecting legal advice of Sabina Downing (Litigation Manager) about potential adverse events provided to employees who need the information to perform their job function.	Attorney-Client Privilege; Work Product	BPVEFILTE R-01- 00120409	BPVEFILTE R-01- 00120410	The entry involves a communication from Kellee Jones (Executive Administrative Assistant) to Rich Bliss (third party consultant) allegedly communicating independent legal advice of Sabina Downing (non-lawyer) "about potential adverse events." Bard's claim of attorney-client privilege should be denied for numerous reasons. First, Bard has failed to establish that the communication involves a request for legal advice from a lawyer. "What is vital to the privilege is that the communication be made in confidence for the purpose of obtaining <i>legal advice from the lawyer</i> ." <u>Richey</u> , 632 F.3d at 566 n. 3 (quoting <u>United States v. Gurner</u> , 474 F.2d 297, 299 (9th Cir. 1973)) (emphasis in original) (other quotation marks and citation omitted). Yet, here Bard is claiming that privilege should attach because a non-lawyer is independently giving legal advice. Second, the communication involves a normal business activity that Bard would have been required to conduct regardless of litigation, i.e. investigation of adverse events and, if and what type of corrective action is necessary. Further any claims of attorney-client privilege has been waived and work product cannot apply as Bard has not established any facts supporting that Mr. Bliss was retained by Bard's lawyers to help prepare for litigation or that he was merely helping Bard's lawyers interpret already privileged material.
Log 6	196	8/7/2009	David Ciavarella	Paul Kowalczyk	Email and attachments seeking legal advice of Greg Dadika, Esquire and Gina Dunsmuir, Esquire about a draft script provided to employees who need the information to perform their job function.	Attorney-Client Privilege			Bard's claim of attorney-client privilege should be denied as Bard has failed to establish that communication reveals a request to or rendering of advice from a lawyer, disclose any facts suggesting legal advice was being provided or solicited, or that confidentiality was maintained. The communication does not include legal personnel. Further, the email does not appear to involve a legal matter. Instead it appears to involve a script being circulated for business reasons such as marketing. Such a document is not a traditionally legal matter as discussed in the <i>Vioxx</i> case, and such does not involve primarily legal advice. This appears similar to Joint Selection No. 36 from <i>Phillips</i> , where the court denied the privilege claim because while the in-house lawyer was being asked to review the attachments allegedly having to do with risk analysis, nothing in the email or the attachments themselves indicated that the document was a confidential communication either providing legal advice or soliciting legal advice. <i>Phillips v. C.R. Bard, Inc.</i> , 290 F.R.D. 615, 656 (D. Nev. 2013).
Log 6	247	4/19/2004	Brian Barry	Mary Edwards	Email reflecting information provided to legal counsel, Donna Passero, Esquire about an adverse event provided to employees who need the information to perform their job function.	Attorney-Client Privilege			Bard's claim of attorney-client privilege should be denied as Bard has failed to establish that communication reveals a request to or rendering of advice from a lawyer, disclose any facts suggesting legal advice was being provided or solicited, or that confidentiality was maintained. The communication is between non-legal personnel and appears to involve Bard conducting its normally required business duty of investigating adverse events.
Log 6	251	6/7/2004	David Ciavarella	Mary Edwards	Email and attachments reflecting legal advice and other information prepared at request of Bard Legal Department about questions for a clinician panel provided to employees who need the information to perform their job function.	Attorney-Client Privilege			Bard's claim of attorney-client privilege should be denied as Bard has failed to establish that communication reveals a request to or rendering of advice from a lawyer, disclose any facts suggesting legal advice was being provided or solicited, or that confidentiality was maintained. The communication is between David Ciavarella (Medical Director) and Mary Edwards (Vice President, Regulatory & Clinical Affairs and appears to relate to a physician panel that Bard conducted as part of its normal course of business to investigate its device failures and determine if corrective action was needed.

Log 6	330	6/21/2013	Denise Marie Barton, John Kaufman Esquire	Document containing legal advice of Denise Marie Barton, Esquire about filter litigation.	Attorney-Client Privilege; Work Product	<p>The entry contains multiple communications, including the disclosed communication between Dr. Kaufman and Ms. Barton, as well multiple undisclosed attached communications between Dr. Kaufman and non-lawyers. Bard's claim of privilege should be denied as Bard has refused to disclose who retained Ms. Barton, provide any facts establishing that communications were being made to obtain or provide legal advice, and confidentiality was not maintained as the communications were made to a third party. There are no facts supporting that Dr. Kaufman was merely helping Bard's lawyers interpret already privileged material. Instead he appears to be providing his own advice and working on non-legal matters. The work product claim should also be denied as Bard has failed to establish that there was impending litigation and/or that the communications would not have been made in substantially similar form but for the prospect of litigation. In particular, the multiple communications between Dr. Kaufman and non-legal employees were clearly made for the purpose of obtaining FDA clearance to market the device.</p>
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EXHIBIT B

BARD

**REGULATORY AFFAIRS MANUAL**

DOCUMENT NO:	<u>RA-STD-002</u>	ORIGINATOR:	<u>Brian Barry</u>
REVISION NO:	<u>08</u>	R.S. HEAD:	<u>Richard Manthei</u>
EFFECTIVE DATE:	<u>Upon Issuance</u>	PAGE NO:	<u>1 OF 11</u> <i>KPM 10-12-00</i>

TITLE: PRODUCT REMEDIAL ACTIONS**I. PURPOSE**

To provide a standard for the development and implementation of a remedial action plan in response to a potential product issue, and to establish a process for the review and approval of that plan.

II. SCOPE

All Divisions, subsidiaries, GTCs and business centers (hereinafter referred to as Divisions), domestic and international, are subject to this standard.

III. DEFINITIONS

Recall: The removal or Field Correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (e.g. seizure). Recall also is the removal, repair or other disposition of a product in clinical study under an approved IDE (including the abbreviated requirements). Recall does not include Market Withdrawal or Stock Recovery.

Note: There is no definition of recall per se in the European Medical Devices Directive. The definition provided in EN46001 is narrower in scope than that used by FDA in that it only applies to recalls or field corrections where there is a risk of death or serious deterioration to the state of health. The UK Medical Devices Agency Draft Guidance on the recall of Medical Device Recalls states that recalls are required whenever "device shortcomings" pose a risk of serious injury to a number of users. Regardless, a global approach must be taken when formulating remedial action plans and, given the developing nature of European guidance on this topic, Bard international RA experts should be consulted during the remedial action planning process.

U.S. FDA Recall Classifications: The numerical designation assigned by the FDA to a particular product recall that indicates the relative degree of health hazard presented by the product being recalled. The classifications are defined as follows:

Class I: is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.



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Enforcement Policy and Recall Guidelines. Actions taken to reduce a risk of health posed by a device or to remedy a violation of the act caused by a device that may present a risk to health are not Market Withdrawals – they are reportable removals/corrections.

Stock Recovery: The removal, retrieval or field correction of a product that has not been marketed or that has not left the direct control of the Division, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

IV. PROCEDURE

A. RESPONSIBILITIES

Division Responsibilities:

The Division Product Assessment Team (Division PAT) is responsible for evaluating product problems which could lead to some type of remedial action and for developing a proposed action plan to deal with such problems. At a minimum, the team shall include the department heads (or designees) of RA, Marketing, Manufacturing, R&D/Engineering and shall be chaired by the Division head of QA. The assigned Medical Director should also be considered a member of the Division PAT and should be consulted throughout the remedial action assessment process.

The Division QA Head is responsible for convening the Division PAT, notifying Corporate VP QA (or designee), leading the Division PAT in the expeditious development of an action plan commensurate with the degree of risk to the patient and for reviewing the proposed action plan with the Division President. The Division QA Head is also responsible for assuring Division implementation of the plan once it is approved by the VP, Corporate Regulatory Sciences, (including coordination and implementation of the plan with other domestic and international business units) and close-out of all corrective/preventive actions outlined in the plan.

The Division RA Head, unless otherwise designated by the Division QA head, serves as alternate to the Division QA Head. The Division RA Head is responsible for all interfaces with FDA and international RA personnel regarding the Division's action plan.

The Division President or Vice President/General Manager is responsible for approving the Division's proposed action plan before that plan is presented to the Corporate Product Assessment Team for review. The Division President or Vice President/General Manager is also responsible for notifying the Group President of the Division's proposed action plan and for ensuring that appropriate resources are made available for timely assessment, implementation and close-out of the potential remedial action.

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Corporate Responsibilities

Corporate Product Assessment Team (Corporate PAT) is responsible for reviewing the Division's proposed action plan and providing recommendations regarding the plan to the VP, Corporate Regulatory Sciences. The Corporate PAT shall be comprised of representatives from Corporate Regulatory Affairs, Medical Affairs, Operations, and Law and shall be chaired by the VP, Corporate Quality Assurance, or designee.

VP, Corporate Quality Assurance is responsible for assuring expeditious development by the Division PAT of an action plan to address a product problem commensurate with the degree of risk to the patient, convening the Corporate PAT, and reviewing the Corporate PAT's recommendations with the VP, Corporate Regulatory Sciences.

VP, Corporate Regulatory Affairs or designee, serves on the Corporate PAT and as the alternate to the VP, Corporate QA in case of absence. Corporate RA is responsible for advising the Division and other members of the Corporate PAT about potential regulatory agency issues/exposure presented by a product problem.

Corporate Medical Affairs the assigned Medical Director is responsible for providing medical consultation to the Division QA Head in developing the plan and for documenting a health hazard evaluation to be included with the Division's proposed action plan. The VP Corporate Medical Affairs serves on the Corporate PAT and is responsible for reviewing the final remedial action plan developed by the Division.

Corporate Law is responsible for advising the Division and other members of the Corporate PAT about the potential risk management exposure of a product problem.

Corporate Operations is responsible for providing review of the Division's proposed Remedial Action Plan and, along with other Corporate PAT Members, assessing the adequacy of the Division's proposed preventive and corrective actions.

VP, Corporate Regulatory Sciences is responsible for making the final decision about the acceptability of the Division's proposed action plan and notifying the Chief Executive Officer (CEO) of that decision.

Corporate MIS is responsible for designating a coordinator to work with Division QA during product remedial actions. The **Corporate MIS Coordinator** is responsible for providing a distribution list for the product subject to the action plan to the Division QA Head within 24 hrs. of receipt of a request from the Division QA Head.

B. GENERAL

1. Each Division shall develop a written procedure to implement the requirements of this

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standard. The local procedure shall identify by position the Division Product Assessment Team (PAT) members and any suitable alternates.

2. FDA will be notified of any Recall, Field Correction, or Safety Alert that affects US customers consistent with the requirements of 21CFR, Part 806, Medical Device Corrections and Removals. When international customers are affected, appropriate notifications will be made to international government agencies by responsible international regulatory coordinators. The Division RA Head is responsible for approving the content of, and providing overall coordination for such notifications, which shall be made only after the VP, Corporate Regulatory Sciences, has approved the Division's action plan. Such notifications shall be documented and a copy of the documentation forwarded to Corporate QA for inclusion in the remedial action file (ref. Appendix E).
3. The Division RA Head will assure that all remedial action reports, if required by FDA under PMA Conditions of Approval or the IDE regulations (21 CFR 812.150(b)(6)), are prepared, reviewed by Corporate Regulatory Affairs and submitted to FDA within the required time period as well.

C. PRELIMINARY ASSESSMENT

NOTE: Refer to Appendix A for a flow chart depicting the process described in sections C-H of this policy.

1. Medical Affairs Consultation:

- 1.1. Sections C-H of this policy shall be followed whenever some type of remedial action is being considered because of potential safety or effectiveness, legal, regulatory, labeling, quality or other problems with the product whether or not a remedial action is eventually taken.
- 1.2. During this preliminary assessment, the assigned Medical Director for the respective Division shall be consulted regarding the potential health hazard represented by the product problem.

NOTE: The medical consultation may be oral at this stage and will depend on the facts known at the time of consultation. As the investigation of the potential product problem proceeds, the Medical Director for the respective Division should be kept fully informed so that he/she can determine if the health hazard or degree of hazard has changed.

- 1.3. Whenever possible, the following background information should be provided to the Medical Director during the medical consultation:
 - Product description, including Information for Use and other pertinent labeling;
 - A description of the problem, including how the problem was discovered, any associated adverse events, patient injuries, etc.;

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- Copies of any associated complaint files;
- A sample of the subject product;
- Information as to the distribution pattern (e.g. distributors, sales reps, etc.), countries where marketed, and quantity of distributed product that may have the problem.

2. Initial Determination

- 2.1. If the Division QA head makes the determination that remedial action does not need to be considered, the reasons for that determination will be documented as part of the Corrective/Preventive Action (CAPA) System and kept on file. Such documentation must include a clear rationale as to why further consideration of remedial action is not required and should include analysis of problem root cause and corrective/preventive action(s). Such documentation should also be reviewed and approved by the Division Head of RA and the Division President/General Manager. If, however, the determination is made by the Division QA Head that some type of remedial action needs to be considered, the Division PAT will be convened and an action plan developed even if the plan recommends no field remedial action (e.g., Recall, Field Correction or Safety Alert). The action plan must also include a final Health Hazard Evaluations.

Evaluation that will be prepared by the Medical Director. The Health Hazard Evaluation and Risk Estimate Guideline formats are provided in Appendix B. Use of these guideline should be considered to assess the overall level of risk.

- 2.2. The Division QA Head shall notify the VP, Corporate Quality Assurance when the Division PAT is convened. The VP, Corporate QA will monitor the deliberations of the Division PAT to assure timely development and implementation of the action plan as described below.
- 2.3. The VP, Corporate QA will assign a lead Division in cases where more than one Division distributes the same product.
- 2.4. The Division PAT should seek the input of the international QA and RA Heads when product has been distributed outside the U.S.

D. DIVISION PAT ACTIVITIES: INVESTIGATION & ACTION PLAN DEVELOPMENT

1. The Division PAT shall evaluate the problem within a reasonable time typically within 5 working days, by considering the following:
- 1.1. The extent of the problem – i.e., is the problem likely to occur again; how many products have been distributed, to what level and in which geographic areas; where is the product now and do any other Divisions market the product;
- 1.2. The health hazard and likelihood of injuries associated with the problem;
- 1.3. The necessity for any immediate internal action, such as putting a "HOLD" on

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distribution of the product involved until a final determination is made should also be considered.

- 1.4. Once a product problem has been investigated and if an actual problem is confirmed, the Division PAT shall develop a written proposed action plan to address the problem and, when appropriate, to address problem product already manufactured.

1.4.1. Time is of the essence in cases where product problems present a reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death (e.g., Class I type recall). In such circumstances the Division PAT shall immediately convene and an action plan will be submitted to Corporate within 2 working days. Additionally, in such cases, any product still under Bard's control shall be placed on immediate distribution hold.

- 1.5. The following are some of the questions that should be considered when developing the action plan:

- Does the problem with the product constitute a violation of the Food, Drug and Cosmetic Act or international regulations? Is the device misbranded/mislabeled? Is the violation minor, or could it represent a potentially a serious health hazard? Does the violation involve a low risk device, or is the product life sustaining or life supporting? Such information is important in evaluating the required remedial action and is also key to understanding how the matter should be handled in international markets as well.
- What is the likelihood of injury?
- Even though there is a possibility of failure, is it a product that is essential to health and for which there is no replacement available? (If the answer is yes, discussions with FDA and other regulatory agencies should be considered prior to implementing any remedial action).
- Would a Safety Alert be more appropriate than other types of remedial action?
- Does the proposed field action require submission of a government Health Ministry/agency report? If the product is distributed outside of the US, any proposed action should be discussed with the appropriate IBC RA personnel to ensure that government-reporting requirements are understood and addressed as part of the action plan.
- Is the problem one that was experienced by the Division or another Division sometime in the past? If so, what action, if any, was taken? Consultation with Corporate QA can be valuable in assessing past history and decision-making.
- Is the problem obvious to the user?

- 1.6. Again, the Divisions are encouraged to seek input and guidance from the Law Department and the corporate heads of RA, QA and Medical Affairs when developing action plans.

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- 1.7. The Division PAT's proposed action plan should follow the format of, and must address the items listed in, Appendix C regardless of whether or not field action is undertaken.

E. CORPORATE PAT SUBMISSION and REVIEW

1. The Division QA Head shall review the Division PAT's proposed action plan with the Division President/General Manager. Once the Division President has reviewed and approved the PAT's proposed plan, the Division QA Head will immediately forward the proposed action plan to the VP, Corporate QA.

NOTE: If the Division PAT cannot reach consensus, the Corporate PAT will be consulted and asked to make a recommendation.

- 1.1. Concurrent with the notification to Corporate, the Division President shall inform the Group President of the Division's proposal.
2. The VP, Corporate QA shall immediately forward copies of the proposed action plan to the members of the Corporate PAT for review. The members of the Corporate PAT shall promptly review the proposal and forward any comments to the VP, Corporate QA. The VP, Corporate QA shall immediately schedule a meeting of the Corporate PAT if there are significant issues that need resolution.
- 2.1. *All action plans that recommend a product Recall or other actions that involve a potentially significant risk to health shall be processed by the Corporate PAT within one day of receipt.*
- 2.2. After review of the Division's action plan by the Corporate PAT, the VP, Corporate QA shall review the Division's proposed action plan and the Corporate PAT recommendation with the VP, Corporate Regulatory Sciences, who will make the final decision. The VP, Corporate QA shall immediately phone and notify the Division QA Head of the VP, Corporate Regulatory Sciences' decision and the Division QA Head shall implement the action based on this notification. The VP, Corporate QA shall document (see Appendix E) the decision within 1 week of the oral notification and forward this documentation to the Division QA Head.

NOTE: The Division may not implement its action plan until the Division QA Head is notified by the VP, Corporate QA (or designee) of the VP Regulatory Science's approval of that plan.

3. The Division QA Head shall finalize the action plan making sure that all elements of Appendix C have been addressed and that any comments from the Corporate PAT have been incorporated into the final document. A copy of the final action plan shall be forwarded to the VP, Corporate QA within 1 week of action plan implementation. A copy of the final action plan shall also be forwarded to the appropriate international QA and RA heads as well.

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F. STATUS REPORTS

NOTE: The following two sections apply only if a reportable field remedial action was taken (e.g., Recall, Corrective Action, Safety Alert).

1. The Division QA Head shall prepare monthly status reports (see Appendix D for content of status reports) and will forward them to Division RA, Corporate QA and Corporate RA.

NOTE: The Division QA Head shall coordinate the action with all distribution centers so that the monthly status report is a combined report reflecting worldwide status of the action.

2. When such notifications are required, IBC RA must provide documented evidence of **Competent Authority** or other government notifications back to the source division.
3. FDA and various international government agencies may also require periodic status reports. The format and frequency of these reports will be dictated by those agencies and will be the responsibility of the Division RA Head. Copies of any status reports submitted to FDA or other government agency shall be sent to Corporate QA.

G. CLOSE-OUT

1. When all reasonable efforts have been made to address/correct the problem and/or remove the product in accordance with the action plan, the Division QA Head shall close out the remedial action with the approval of the VP, Corporate QA. The close-out shall be in the form of a final status report to the Division RA Head, and the VP, Corporate QA. The Division QA Head shall also review the Division's file for the completed action and will assure that all appropriate documentation is in place and that any extraneous information is destroyed.
2. When applicable, the Division RA Head shall submit a close out report to FDA and/or other appropriate government agencies.
 - 2.1 Upon receipt, the Division RA Head shall forward a copy of the termination notice from FDA, to Corporate QA. If a termination notice is not received from FDA within 3 months following submission of the close out report, Division RA will request same from FDA and will follow-up periodically with them until a termination notice is received.
3. The VP, Corporate RS shall notify the Chief Executive Officer of the action close-outs, i.e., both internal close-out and FDA close-out.

H. RECORD RETENTION

1. The Division QA Head shall assure that the following records are permanently retained:

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- 1.1 the proposed action plan reviewed by the Corporate PAT;
- 1.2 the approval form from the Corporate PAT; the final action plan and all supporting documentation to the plan (e.g., distribution lists.)
- 1.3 all FDA and foreign government communications regarding the action.

V. REFERENCES

"Methods for Conducting Recall Effectiveness Checks", Prepared by The Food and Drug Administration, June 16, 1978.

"FDA Draft Guideline on Medical Device Notification and Voluntary Safety Alerts", FDA, March, 1984.

21CFR Part 810, Medical Device Recall Authority

21 CFR Part 7, Enforcement Policy and Recall Guidelines.

21CFR, Part 806, Medical Devices; Reports of Corrections and Removals

UK Medical Devices Agency Draft Document on the Recall of Medical Device (July 2000)

VI. IMPLEMENTATION

The provisions of this standard will be implemented within sixty days of the effective date.

VII. REVISION RECORD

<u>Rev #</u>	<u>Rev. Date</u>	<u>Description</u>	<u>Rev. By</u>
00	06/18/80	Original	D.F. Grabarz
01	4/16/81	Administrative changes, Definition of "recall" and "market withdrawal" were simplified.	D.F. Grabarz
02	1/10/83	Administrative changes.	D.F. Grabarz F.R. Bonanni
03	10/1/88	Additional administrative requirements to be implemented by various Corporate departments.	D.F. Grabarz F.R. Bonanni C.V. Beath
04	12/27/91	Changed to new format. CDA #92-011	C.V. Beath

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- | | | | |
|----|---------|---|---------------|
| 05 | 7/23/93 | Addressed Group responsibilities; clarified international responsibilities; changed title; and other minor changes.
CDA #93-008 | C.V. Beath |
| 06 | 2/01/94 | Reassigned CEO responsibilities to V.P., Corporate RS
CDA #94-003 | S. Austermann |
| 07 | 3/1/95 | Reassigned Group responsibilities to Corporate; added definitions for "Medical Device Notification", "Notification Order", "Safety Alert" and "Unreasonable Risk of Substantial Harm"; clarified responsibilities of V.P., Corporate QA; added GTC to Scope; clarified purpose of policy; replaced certain Appendices with references; and other minor changes.
CDA #95-008 | C. V. Beath |
| 08 | | Update titles and reformat in new Scientific Affairs "standard" format. Clarified data Requirements during initial medical consultation and updated standard to incorporate updated FDA and International guidance. Added Risk Risk Estimation Guideline to Appendix B. Added Corporate Operations to the Corporate PAT. Added Emphasis to requirement for obtaining International RA Input on proposed remedial action plans. Added statement #2 to Section F regarding the need for IBCs to provide source division with documented evidence of competent authority notification. | B. Barry |

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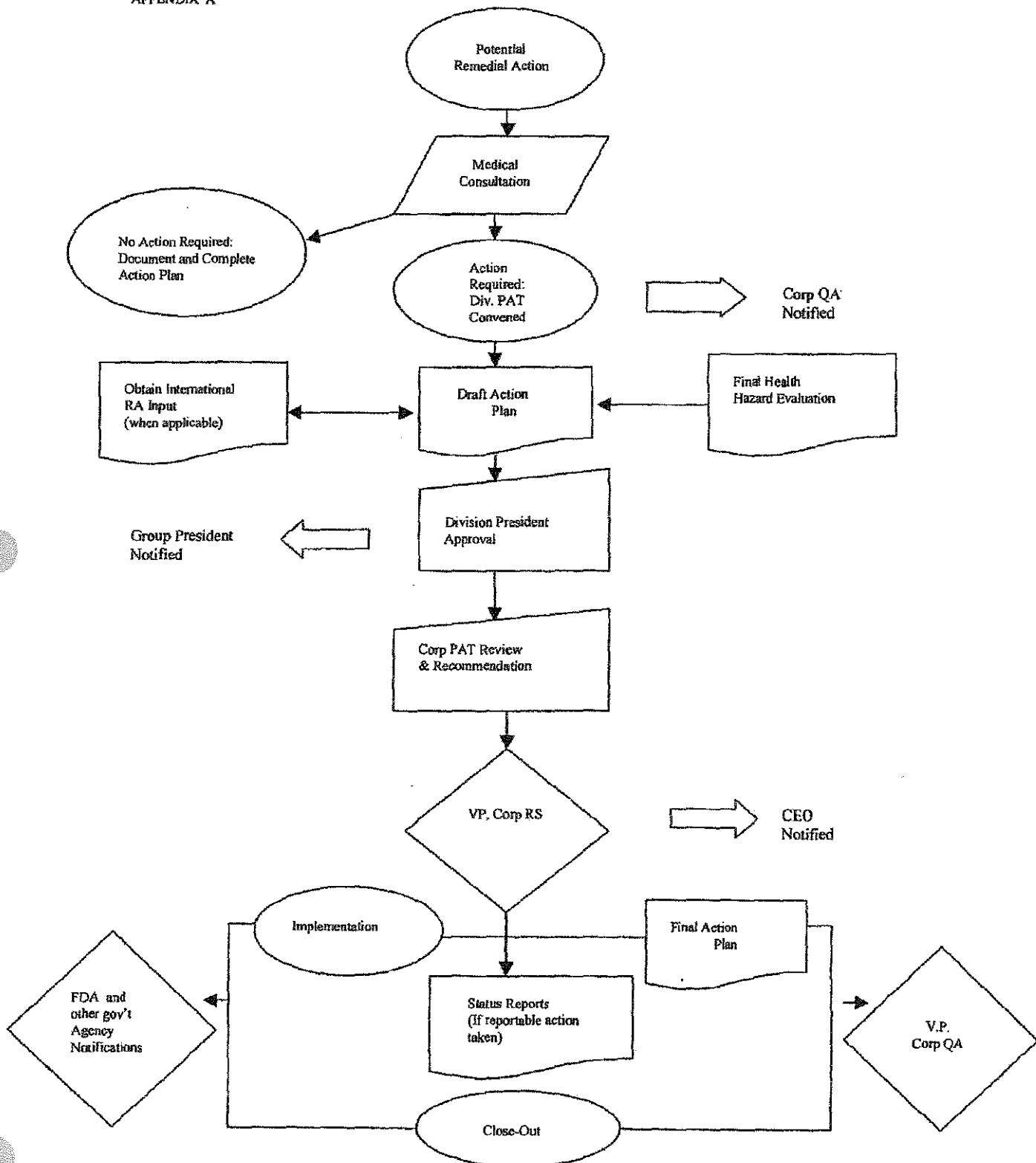
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Appendix A

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APPENDIX A



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Appendix B

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APPENDIX B

Health Hazard Evaluation and Risk Estimation Guideline

DATE:

TO:

FROM: _____, MD

SUBJECT: HEALTH HAZARD EVALUATION: PRODUCT NAME

Summary:

Conclusion:

Description of the Problem:

The Actual Occurrence of Injuries:

Human Exposure to the Problem:

General Consequences:

Population Exposed to the Risk:

Mitigating/Predisposing Factors in the Population at Risk:

Nature & Seriousness of the Risk:

Likelihood of Occurrence of the Problem:

Likelihood of Harm if the Problem Occurs:

Is the Product Essential to Health:

Is there an Alternative Available:

Must the Problem Device be Removed or Corrected Surgically:

Is the Problem Expected & Within an Acceptable Statistical Range:

Can the Problem be Corrected in the Field:

Is the Problem or Health Hazard Obvious to the User:

Can the Product Continue to be Used with Proper Warnings:

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RISK ESTIMATION GUIDELINES FOR HEALTH HAZARD EVALUATIONS¹

C.R. BARD, Inc. CORPORATE MEDICAL AFFAIRS (rev. 03/31/2000)

> CATEGORIES FOR THE POTENTIAL SEVERITY² OF THE POTENTIAL HAZARD:

CATASTROPHIC ("Life Threatening"): A failure that can by itself cause death, system loss or a significant disability to a patient or device user. For example, the device failure can directly result in organ failure, limb loss or death.

CRITICAL ("Severe/Significant"): A failure that can contribute to a death, severe injury, permanent significant disability or severe occupational illness in a patient or device user. For example, the device failure can result in a cascade of events leading to death, serious injury, additional surgical procedures or increased user risk (e.g., exposure to blood borne pathogens)

MARGINAL ("Limited"): A failure that can cause transient minor injury to a patient or user. The injury may require treatment but has no long term life limiting consequences. For example, the patient or user is accidentally stuck with a sterile sharp due to a protective component failure.

NEGLIGIBLE ("None"): No injury. For example, the device fails to work but the user can get another one to complete the task.

> CATEGORIES FOR THE ACTUAL OR STATISTICALLY DERIVED FREQUENCY OF THE POTENTIAL HAZARD:

FREQUENT	$X > 10^{-1}$	Greater than 1 in 10 uses of the product	(>0.1)
PROBABLE	10^{-1} to 10^{-2}	1 in 10 to 1 in 100 uses of the product	(0.01 to 0.1)
OCCASIONAL	10^{-2} to 10^{-3}	1 in 100 to 1 in 1,000 uses of the product	(0.001 to 0.01)
REMOTE	10^{-3} to 10^{-6}	1 in 1000 to 1 in 1,000,000 uses of the product	(0.000001 to 0.001)
IMPROBABLE	$10^{-6} > X$	Less than 1 in 1,000,000 uses of the product	(<0.000001)

> HAZARD RISK ASSESSMENT MATRIX:

Frequency Category	Severity Category			
	Catastrophic	Critical	Marginal	Negligible
Frequent ($X > 10^{-1}$)	1	3	7	13
Probable (10^{-1} to 10^{-2})	2	5	9	15
Occasional (10^{-2} to 10^{-3})	4	6	11	18
Remote (10^{-3} to 10^{-6})	8	10	14	19
Improbable ($10^{-6} > X$)	12	15	17	20

> MANAGEMENT GUIDANCE HAZARD RISK INDEX ACTION TABLE:

Hazard Risk Matrix Number	Action/Acceptability
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¹ Derived from MIL-STD-882C ("System Safety Program Requirements"), FDA Regulatory Procedures Manual, Chapter 7 and AAMI/ISO 14971-1-1998 (Medical devices-Risk management-Application of risk analysis)

² "The consequences of the worst credible mishap"

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1-5	Unacceptable – Must be corrected
6-9	Undesirable – Design Review Team must review
10-17	May be Acceptable with Management review
18-20	Usually Acceptable without further review

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**Appendix C
Action Plan Outline****1. Product Description and Intended Use**

This section should contain the name and catalog number of the product involved and a brief description of its intended use. A copy of a current product labeling and Information for Use should also be included.

2. Manufacturer/Distributor

This section should list the site(s) of manufacture (including outside contractors) and the division(s) that market the product, both domestic and international, if applicable.

3. Identification of Problem

This section should describe how knowledge of the problem occurred and the subsequent follow-up activities. It should include actual numbers and results of testing performed. For example, if you became aware of the problem through a complaint, the number, date, and source of the complaint, along with QC testing results of inventory and retained samples, should be listed. **This section should also identify the ROOT CAUSE of the problem.**

4. Medical Evaluation

Attach the Health Hazard Evaluation prepared by the Medical Director for the respective Division.

5. Number of Units and Lots Involved

Actual lot numbers and total number of units per lot number amounts should be stated here and totaled.

6. Distribution of Units

This section should contain a breakdown of the number of units and how they were distributed. For instance, how many went directly to hospitals, distributors, or sales reps and to what countries. Also summarize exactly how many distributors and hospitals will need to be contacted, if contact is part of the action plan.

7. Action Plan

This section should include the following information about the plans to address the product problem:

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- 7.1 If shipments have been discontinued, state date of occurrence;
- 7.2 Describe the type, scope, and depth of the action (e.g., Recall, Safety Alert - all lots, one lot - user, wholesaler) and the rationale for the scope (i.e., why is the action limited to the described scope);
- 7.3 If the action involves communication to sales reps and/or accounts, list the various levels of communication (e.g., sales force, distributors, hospitals), the method of communication and follow-up (e.g., telephone, letter) and the dates of contact; also include the telephone script or text for all such communications;
- 7.4 If the action involves correction in the field, describe the method of correction, who will perform the field correction, how it will be communicated to the customer and the individuals performing the field correction, and how the correction will be verified; also include text of all such communications;
- 7.5 If the action is a Recall, Field Correction or Safety alert, describe the effectiveness checks to be used;
- 7.6 If the action is a Recall, Field Correction or safety alert, list the date FDA and/or government agencies outside the U.S. to be notified and by whom. Include copies of any planned communications whenever possible; and
- 7.9 Describe the planned disposition of problem product (e.g. rework, scrap, etc.).

8. Product Correction

This section should contain the steps that have been taken to correct the problem and prevent its recurrence. Target dates for completion of all action items must be included.

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APPENDIX D – MONTHLY RECALL STATUS REPORT FORMAT

The monthly status reports submitted to Corporate should include the following information where applicable.

NOTE: Incorporate both U.S. and international results into one overall report.

1. Total quantity of product to be recalled;
2. Total number of consignees (sales representatives, hospitals, distributors, etc.) to be notified of recall;
3. Number of consignees notified of recall;
4. Number of consignees responding to the recall communication and total quantity of product on hand as noted by these responding consignees;
5. Number of consignees not responding;
6. Quantity of product returned or corrected or otherwise accounted for;
7. Quantity of product unaccounted for; and
8. Number and results of effectiveness checks that were made.

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Appendix E

Division Notification

To: Division QA Head cc: Corporate PAT
From: V.P., Corporate QA
Subject: Division Remedial Action Plan
[Plan Date or Other Reference]

Date:

The above action plan was reviewed by the Corporate PAT:

Date Reviewed:

Corporate PAT reviewers:

Corporate Law-

Corporate RA-

Corporate MA-

Corporate QA-

Corporate Operations -

Corporate PAT Recommendations:

Recommendations were presented to the V.P., Corporate RS

By:

Date:

Decision of the V.P., Corporate RS:

EXHIBIT C

Troy Brenes

From: Kate Helm
Sent: Wednesday, March 02, 2016 11:58 AM
To: lincoln.combs@gknet.com; tbrenes@breneslawgroup.com
Cc: Richard North; Matthew Lerner
Subject: Bard MDL privilege log meet and confer
Attachments: 20160302143814700.pdf

Gentlemen: attached is the list of additional documents Bard is producing or producing in a redacted form under the 502d Order based on our recent meet and confer sessions. In making this production, as with the prior production, Bard does not agree that the documents are non-privileged. Further, in producing these to address this dispute, Bard does not agree or waive that other documents addressing the same or similar topics or other documents to or from the same authors or recipients should be produced. As you know 502d expressly states that there is no waiver.

Kate

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If you are not the named addressee, you are not authorized to read, print, retain, copy or disseminate this message or any part of it. If you have received this message in error, please notify the sender immediately either by phone (800-237-2000) or reply to this e-mail and delete all copies of this message.